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Studien zur Optimierung der perioperativen Versorgungsqualität in der pädiatrischen Visceralchirurgie und Urologie

Kumulative Habilitationsschrift
zum Erlangen der Venia Legendi für das Fach Kinderchirurgie

vorgelegt von Dr. med. Martina Heinrich
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Einleitung

Die Ära der europäischen kinderchirurgischen Kultur begann mit dem türkischen Chirurgen Serafeddin Sabuncuoglu im 15.Jahrhundert, der erstmalig in seiner Operationslehre kinderchirurgische Eingriff genau dokumentierte [1]. Im 19.Jahrhundert entwickelten sich dann auch in Deutschland erste kinderchirurgische Keimzellen und am 21.September 1957 wurde von Prof. Dr. Anton Oberniedermeier im Dr. von Haunerschen Kinderspital die "Arbeitsgemeinschaft Deutscher Kinderchirurgen" innerhalb der Deutschen Gesellschaft für Chirurgie gegründet, welche 1963 umbenannt wurde in "Deutsche Gesellschaft für Kinderchirurgie e.V." (DGKCH) [2].

Den höchsten Stellenwert für das chirurgisch kranke Kind hat laut der Deutschen Gesellschaft für Kinderchirurgie das Recht auf eine bestmögliche Behandlung in einer speziell auf Kinder ausgerichtet Einrichtung. Dies wurde 2001 in der „Kyoto Declaration of Pediatric Surgery“ der „World Federation of Associations of Pediatric Surgery“ (WOFAPS), die auch von der Deutschen Gesellschaft für Kinderchirurgie ratifiziert wurde, gefordert [3].

Um dies im klinischen Alltag zu gewährleisten, muss konsequenterweise eine stetige Optimierung der Versorgungsqualität in den einzelnen Behandlungsabläufen und –strukturen erfolgen. Hierfür benötigt es einen mehrdimensionalen Ansatz zur Verbesserung der Qualität der Struktur der medizinischen Einrichtung, des Fortbildungsstandes der Mitarbeiter und der verschiedenen medizinische Behandlungsergebnisse.

In der vorliegenden Arbeit zur patientenorientierten klinischen Forschung wird exemplarisch in vier verschiedenen Arbeitsfeldern anhand von ausgewählten innovativen, mehr-dimensionalen Ansätzen gezeigt, dass eine Optimierung der perioperativen Versorgungs-

qualität für Kinder mit angeborenen oder erworbenen chirurgischen Erkrankungen möglich ist.

Arbeitsfeld I: Trainingsmodelle zur Verbesserung der technischen sowie nicht-technischen Fertigkeiten in der Kinderchirurgie

(A) Endochirurgisches Trainingsmodell in der Kinderchirurgie

Die Etablierung eines endochirurgischen Trainingsmodells mit einem New Zealand weißen Kaninchen wurde implementiert und der Stellenwert dieses Tiermodells in der Ausbildung anhand einer Studie zum Erlernen einer laparoskopischen Darmbiopsie gezeigt.

(B) Simulationsbasiertes Teamtraining in der pädiatrischen Traumaversorgung

Entwicklung und Durchführung eines Ausbildungskonzeptes für ein interdisziplinäres Teamtraining in einem simulierten Schockraum, das in der anonymisierten Befragung der Teilnehmer als sehr realitätsnah und hoch relevant für die tägliche Arbeitsroutine beurteilt wurde sowie die medizinischen und nicht technischen Fähigkeiten verbesserte.

Arbeitsfeld II: Weiterentwicklung von Therapiekonzepten durch eine systematische Analyse von postoperativen Langzeitverläufen und Komplikationen in der Kinderchirurgie

(A) Abwägung der Indikationsstellung unter Einbeziehung patientenorientierter Parameter

Anhand einer retrospektiven Datenerhebung und eines aktuellen Interviews mit den Eltern von Kindern mit einer gastroösophagealen Refluxkrankheit und zusätzlichen Risikofaktoren konnte gezeigt werden, dass die Einbeziehung der Bewertung der klinischen Ergebnisse durch

die Eltern ein wichtiger Bestandteil in der Beurteilung der Indikationsstellung und Effektivität der Anti-Reflux-Chirurgie bei Kindern ist.

(B) Kritische Analyse von Rezidiveingriffen und deren Komplikationen bei Kindern mit Morbus Hirschsprung

Durch eine systematische Aufarbeitung von komplizierten Verläufen von Kindern mit Morbus Hirschsprung zeigte sich, dass die meisten Komplikationen, die zu weiteren chirurgischen Operationen führten vermeidbar gewesen wären. Postoperative Komplikationen sowie eine verzögerte Behebung der klinischen Symptome waren häufig.

Arbeitsfeld III: Optimierung der Schmerztherapie in der Kinderchirurgie

(A) Langfristige Optimierung der postoperativen Schmerztherapie bei Kindern

In einer prospektiven Interventions-Studie durch einen interdisziplinären Ansatz konnten wir zeigen, dass eine Verbesserung der Qualität der postoperativen Schmerztherapie durch regelmäßige Fortbildungen, regelmäßiges Training der Mitarbeiter im Rahmen von Inhouse-Schulungen sowie durch strukturelle Verbesserungen erreicht werden kann.

(B) Etablierung verschiedener Methoden zur Analgosedierungen in der Kinderchirurgie

Zur Optimierung von ambulanten chirurgischen Interventionen im Kindesalter, welche aufgrund von fehlender Kooperation und Unruhe oft ungleich schwieriger als beim Erwachsenen sind, wurde in zwei prospektiven Studien für geplante Verbandswechsel nach thermischen Verletzungen bzw. kleinen chirurgischen Eingriffen in der Notfallambulanz Konzepte zur Analgosedierung eingeführt und überprüft.

Arbeitsfeld IV: Optimierung diagnostischer Therapiekonzepte in der Kinderurologie zur Vermeidung von Strahlenbelastung

(A) Rechtfertigung einer routinemäßigen invasiven Diagnostik zum Ausschluss eines vesicorenalen Reflux (VUR) bei Kindern mit Ureterabgangsstenose (UAST)

In einer Multizenterstudie konnte die Empfehlung der aktuellen Leitlinien bei Kindern mit UAST routinemäßig ein invasives sowie mit einer Strahlenbelastung verbundenes Miktionszystourethrogramms (MCU) durchzuführen, um einen begleitenden VUR auszuschließen, wiederlegt werden. Als Risikofaktoren für einen VUR zeigten sich nur rezidivierende HWI und eine sonographische Harnleiterdilatation.

(B) Optimierung der postoperativen Verlaufskontrolle mittels MAG3 Nierenszintigraphie nach Korrektur einer einseitigen Ureterabgangsstenose (UAST) im Kindesalter

In einer retrospektiven Evaluation von Patienten mit isolierter unilateraler UAST zeigte sich unter dem aktuellen therapeutischen Vorgehen eine sehr geringe Wahrscheinlichkeit eines Funktionsverlustes der Partialfunkton der betroffenen Nieren von nur 2,5% mit einer sehr guten Effektivität der Pyeloplastik von 98,3%. Wiederholte Szintigraphien mit Strahlenbelastung sind routinemäßig nicht notwendig.

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1) Büyükünal SN, Sari N. Serafeddin Sabuncuoglu, the author of the earliest pediatric surgical atlas: Cerrahiye-i Ilhaniye. J Pediatr Surg, 1991;26(19):1148-51

2) Grosfeld JL. World federation of associations of pediatric surgeons. Declaration of pediatric surgery. J Pediatr Surg 2001; 36(12):1743

3) www.dgkch.de

Eigene wissenschaftliche Arbeiten zum Habilitationsprojekt

I. Trainingsmodelle zur Verbesserung der technischen sowie nicht-technischen Fertigkeiten in der Kinderchirurgie

Dieser Aspekt des Habilitationsprojektes beschäftigte sich mit der Rationale, das in der Kinderchirurgie oft nur eine kleine Anzahl an Fällen bzw. operativen Eingriffen einer hochspezialisierten und anspruchsvollen Therapie gegenüber stehen. Außerdem sind diese fortgeschrittenen Eingriffe gerade in der minimal invasiven Chirurgie teilweise mit einer langen Lernkurve verbunden [Georgenson 2000]. Gefordert sind eine kinderchirurgische spezifische Ausbildung und Trainingsmöglichkeiten von diesen speziellen technischen, aber auch nicht-technischen Fertigkeiten [Till 2001, Kellnar 1997]. In der Pädiatrie wurden zur Verbesserung des Notfallmanagments bei lebensbedrohlichen Ereignissen bei Kindern, wie zum Beispiel Atems- oder Kreislaufmanagement, spezielle simuationsbasierte interdisziplinäre Kurse etabliert, da solche lebensbedrohlichen Notfälle bei Kindern selten sind und die Behandlungsteams vor eine sehr großer Herausforderung stellen [Weinberg 2009, PAEDSIM e.v. Tübingen]. Modelle aus der Erwachsenenmedizin sind oft nicht übertragbar auf die kindlichen Verhältnisse und bedürfen einer Modifizierung. Anhand von zwei exemplarischen Studien im Bereich der Trainingsmodelle in der minimal invasiven Chirurgie bei Kindern und dem simulationsbasierten Teamtraining in der pädiatrischen Traumaversorgung werden in zwei sehr sensiblen und anspruchsvollen Bereichen Modelle aufgezeigt, die Trainingsmöglichkeiten zu verbessern und deren Effektivität beschrieben.

Literatur:

1) Georgenson KE, Owings E. Advances in minimally invasive surgery in children. Am J Surg 2000;180:362-364

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4) Weinberg ER, Auerbach MA, Shah NB. The use of simulation for pediatric training and assessment. Curr Opin Pediatr 2009;21(3):282-287

5) www.paedsim.org

A Endochirurgisches Trainingsmodell in der Kinderchirurgie

Publikation: *Heinrich M, Tillo N, Kirlum HJ, Till H. Comparison of different training models for laparoscopic surgery in neonates and small infants. Surgical Endoscopy, 2006 Apr;20(4):641-4*

Hintergrund: In der minimal invasiven Chirurgie bei Kindern hat sich im letzten Jahrzehnt eine rasche Weiterentwickelung gezeigt. Diese sehr anspruchsvollen Operationen erfordern eine sehr große Erfahrung und hoch spezialisierte technische Fertigkeiten. Dem gegenüber steht eine kleine Anzahl an Eingriffen und somit limitierter persönlicher Erfahrung des einzelnen Chirurgen. Die Forderung nach Trainingsmöglichkeiten zur Etablierung neuer Operationstechnik oder zur Ausbildung der Assistenten für minimal invasive Operationen am Kind ist notwendig. Die Größe der gängigen Pelvitrainer oder Tiermodelle am Schwein simulieren nicht adäquat die Größenverhältnisse beim Neugeboren oder Säugling. In unserer Arbeitsgruppe wurde ein endochirurgisches Trainingsmodell mit einem New Zealand weißen Kaninchen in unserer Klinik für die Ausbildung in der minimal invasiven Chirurgie implementiert und für verschiedene Eingriffe (Gastrostomie, Kolostomie, Darmbiopsie, Lungenbiopsie, Anastomose des Ösophagus) etabliert. Das Gewicht der Kaninchen sowie das Ausmaße des Thorax und Abdomens sind vergleichbar mit dem eines Neugeborenen.

Methodik: Um die Ausbildung der kinderchirurgischen Assistenten für minimal invasive Eingriffe zu verbessern und gleichzeitig zu evaluieren, welchen Stellenwert das Kaninchen-Tiermodell in der kinderchirurgischen Ausbildung hat, wurde von unsere Arbeitsgruppe eine Studie zum Erlernen einer laparoskopischen Darmbiopsie mit intrakorporaler Naht durchgeführt. Zwölf kinderchirurgische Assistenzärzte wurden in zwei Gruppen randomisiert. Alle Teilnehmer durchliefen zunächst drei Basisübungen an einem an die kleineren Größenverhältnisse angepassten Pelvitrainer. Gruppe A übte achtmal eine Darmbiopsie an

diesem Pelvitrainer und Gruppe B übte entsprechend am Kaninchenmodell. Jeder Teilnehmer führte die Operation bei einem abschließenden Test am Kaninchen durch. Zur Auswertung der durchgeführten Darmbiopsien wurde ein eigens für die Studie entworfener und validierter Index verwendet, der eine Beurteilung der Qualität der Darmbiopsie und der persönlichen Fertigkeiten für jede einzelne Operation der Teilnehmer ermöglichte (Tabelle 1). Am Ende erfolgte eine Wiederholung der drei Basisübungen am Pelvitrainer.

Score Criteria	(Points)	Best score (points)
Complication		
Perforation	No (20) Yes (0)	20
Concomitant injury	No (8) Yes (0)	8
Good tissue handling	Yes (8) Tear (4) No (0)	8
Suture		
Suture removal	No (8) Yes (0)	8
Fixed suture	Yes (8) No (0)	8
Needle grasping	0-2x (8) 3-4x (4) >5x (0)	8
Suture time	6 min (20) 7-10 min (10) >10 min (0)	20
Biopsy		
Successful	Yes (8) No (0)	8
Total Score		100

Tabelle 1: Index für die Evaluierung der Qualität der Darmbiopsie und der persönlichen Fähigkeiten jeder durchgeführten Operation jedes Teilnehmers, mit einem bestmöglichen Ergebnis von 100 Punkten.

Ergebnisse: Es zeigte sich kein signifikanter Unterschied in der Auswertung der drei Basis-Übungen im Pelvitrainer zu Beginn der Studie zwischen den beiden Gruppen, somit war von einer gleichen Ausgangssituation in den beiden Gruppen auszugehen. Die Lernkurve über die

acht Übungsoperationen (Darmbiopsie), die Anhand des Gradienten der linearen Regression des ausgewerteten Index beurteilt wurde, war signifikant besser in der Pelvitrainergruppe (b=4,48 Gruppe A am Pelvitrainer, b=1,75 Gruppe B am Kaninchenmodell). Im Abschlusstest verschlechterte sich der Index der Gruppe A wieder auf Niveau der ersten Übungsoperation. Die Ursache hierfür liegt wahrscheinlich an der in-vivo Bauchhöhle, was in einer erhöhten Rate an Komplikationen und verlängerten Nahtzeit resultierte. Somit kann der Lerneffekt, der im Pelvitrainer erworben wurde, nicht vollständig in das in-vivo Modell übertragen werden.

Schlussfolgerung**:** Zusammenfassend sind Basistechniken der minimal invasiven Chirurgie gut im Pelvitrainer erlernbar. Spezielle live intraoperative Bedingungen sind aber wichtige Bestandteile in der Ausbildung der pädiatrischen minimal invasiven Techniken um einen möglichst sicheren Ablauf einer Operation am Neugeborenen / Kind zu gewähren. Somit erscheint eine schrittweise Ausbildung vom Pelvitrainer über das Kaninchenmodell sinnvoll. Im Anschluss an unsere Studie wurde in verschiedenen Trainingskursen für kinderchirurgische minimal invasive Techniken das Kaninchenmodell eingeführt.

Diese Studie unterstreicht die Notwendigkeit einer an die pädiatrischen Verhältnisse angepasste Trainingsmöglichkeiten für das Erlernen von technische Fertigkeiten von minimal invasiven Eingriffen.

B Simulationsbasiertes Teamtraining in der pädiatrischen Traumaversorgung

Publikation: *Lehner M, Heimberg E, Hoffmann F, Eppich W, Heinzel O, Kirschner HJ, Heinrich M. Evaluation of a pilot project to introduce simulation-based team training to pediatric surgery trauma room care. Int J Pediatr Epub 2017 Feb;14: ID 9732316*

Hintergrund: Unfälle sind eine der häufigsten Ursachen für die Mortalität bei Kindern, die älter als ein Jahr sind, sowie für schwerwiegende verbleibende Schädigungen. Die Behandlung von schweren Verletzungen und lebensbedrohlichen Zuständen sind eine sehr große Herausforderung für die behandelnden Teams im Schockraum, auch in Level 1 Trauma Zentren für Kinder. Einige Studien konnten massive Defizite aufzeigen in der Versorgung von schweren pädiatrischen Traumata. Dies betrifft insbesondere die nicht-technischen Fertigkeiten. Spezielle simulationsbasierte Schulungen der Teams sind in verschiedenen medizinischen Bereichen mit sehr hohen Anforderungen schon etabliert worden. In Deutschland wurde bisher noch kein Simulationstraining für interdisziplinären Teams im Schockraum für die pädiatrische Traumaversorgung angeboten.

Methodik und Patienten: Es wurde eine Simulationstraining für 14 Ärzte und vier Pflegekräfte, die alle im Alltag in der Kinderchirurgie, Kinderänästhesie, Kinderintensivmedizin oder Notfallmedizin schon seit mehr als sechs Jahre in der Schockraumversorgung bei Kindern tätig waren, im Tübinger Patientensicherheits- und Simulationszentrum (TüPASS) durchgeführt. Zwei Wochen vor Beginn erhielt jeder Teilnehmer die aktuellen, offiziellen Leitlinien des ERC (European Resuscitation Council) zur theoretischen Vorbereitung. Der Kurs dauerte 1,5 Tage mit einer theoretischen Einführung über drei Stunden, einer Einführung in den Simulator und praktischen Übungen zu technischen Fertigkeiten in der Schockraumversorgung. Anschließende erfolgten sechs

Szenarios ausschließlich aus dem Bereich der pädiatrisch traumatischen Schockraumversorgung mit verschiedenen Schwerpunkten aus dem diagnostischen und therapeutischen Algorithmus der EPLS (European Pediatric Life Support) und ATLS (Advanced Trauma Life Support) Kurse sowie verschiedenen CRM (Crew Resource Management) Lernzielen. Der Zeitplan gab ein Szenario von 15 Minuten vor mit anschließendem video-basiertem Debriefing durch zwei interdisziplinäre, multiprofessionelle Instruktoren. Die Evaluation des Kurses durch die Teilnehmer erfolgte anhand eines anonymisierten Fragebogens vor und nach dem Kurs mit einer Selbsteinschätzung in Bezug auf medizinische Kompetenz und CRM Aspekte.

Ergebnisse: Die Teilnehmer beurteilten den Kurs als sehr realistisch und praxisrelevant für den Alltag. Das detaillierte, videobasierte Debriefing wurde als sehr positiv evaluiert und keiner der Teilnehmer fühlte sich dadurch vorgeführt. Individuelle Aspekte dieses Kurses zeigten eine nachweisbare Verbesserung in allen medizinischen Bereichen [Luftwege (NS, nicht signifikant), Zirkulation (NS), Polytrauma (NS), schweres SHT (NS), kardiopulmonale Reanimation ($p< 0,001$), Setzen von Prioritäten ($p>0,001$), Kommunikation (NS)].

Zusammenfassung: Dieses Pilotprojekt zeigt die erste Etablierung eines praxisrelevanten simulationsbasierten Team-Trainings in der Schockraumversorgung von pädiatrischen Traumata in Deutschland. Basierend auf das Kurskonzept der PAEDSIM-Arbeitsgruppe konnte ein relevantes Konzept ausgearbeitet werde mit Schwerpunkt auf nicht-technischen Fertigkeiten. Die Teilnehmer realisierten selbst insbesondere die Notwendigkeit einer klaren Struktur des Teams, vor allem in komplexen Situationen. Das videobasierte Debriefing ist dafür essentiell und wurde von den Teilnehmern als hilfreich eingestuft, sie fühlten sich nicht unwohl oder vorgeführt. Ziel ist diese Art von hochqualitativer Fortbildung in die einzelnen

Kliniken vor Ort zu bringen und möglichst flächendeckend dieses Teamtraining in situ durchzuführen.

Diese Studie zeigt, dass es notwendig ist, ein simulationsbasiertes Teamtraining in der Schockraumversorgung von pädiatrischen Traumata mit Schwerpunkt auf nicht-technische Fertigkeiten anzubieten. Die Teilnehmer waren einem videobasierten Debriefing gegenüber aufgeschlossen und erkannten die für sie praxisrelevanten Fortschritte.

II. Weiterentwicklung von Therapiekonzepten durch eine systematische Analyse von postoperativen Langzeitverläufen und Komplikationen in der Kinderchirurgie

Dieser Aspekt des Habilitationsprojektes beschäftigte sich mit der Rationalen, dass in der Kinderchirurgie die vorhandenen Leitlinien oder Therapiemepfehlungen auf keinem sehr hohen Qualitätsniveau sind. In der Arbeitsgemeinschaft der Wissenschaftlichen Medizinischnen Fachgesellschaften e.V. (AWMF) sind aus den insgesamt 24 aktuellen Leitlinien der Deutschen Gesellschaft für Kinderchirurgie (DGKCH) 17 Leitlinien auf der Stufenklassifikation S1 (Handlungsempfehlung von Expertengruppen) und 11 aus der Stufenklassifikation S2k (konsensbasierte Leitlinie) [www.awmf.org]. Ursächlich sind fehlende prospektive, randomisierte Multizenter-Studien auf deren Grundlage die Leitlinien angehoben werden könnten. In den letzten 20 Jahren hat sich der Anteil an Level 1 Studien (randomisierte, kontrollierte Studien, RCT) in der gesamten medizinischen Fachliteratur nicht verändert und liegt bei nur 10%, der Anteil an Beobachtungsstudien ist gestiegen auf 40% [Wyler 2015]. Der Anteil an RCT in der Fachliteratur liegt bei Kindern noch niedriger. In einer Auswertung der Fachliteratur (MEDLINE, EMBASE, LILACS, CENTRAL) zu kritisch kranken Kindern wurden bisher 11.449 Fachartikel veröffentlicht und davon nur 248 als randomisierte, kontrollierte Studien (2.2%) [Duffett 2013]. Von den 248 RCT waren nur 24% mit kinderchirurgischen Krankheitsfällen vertreten. Daher fehlen diese kontrollierten Studien in der Kinderchirurgie und Fragen zur Diagnostik und Therapie werden oft nur anhand von einzelnen Fallbeschreibungen oder monozentrischen, retrospektiven Erfahrungsberichten und teilweise anhand von Daten aus der Erwachsenenmedizin ohne ausreichender kinderchirurgischer Daten beantwortet. Diese Beispiele zeigen, dass es gerade in der Kinderchirurgie notwendig ist wichtige Fragestellung anhand der zur Verfügung stehenden

methodischen Möglichkeiten zu beantworten. Hierfür haben methodisch gut strukturierte Beobachtungsstudien einen großen Nutzen sowie bei genau gestellter Indikation und Durchführung eine hohe Aussagekraft und liefern verwertbare Ergebnisse [Rosendaal 2001]. Bei einem Ansatz einer qualitativen und patientenorientierten Forschung bei der verschiedene Interventionen unter Alltagsbedingungen inkludiert und analysiert werden können je nach Fragestellung und vor allem Qualität der erhobenen Daten eine gute Evidenz der Daten resultieren, die höher liegen kann als bei kontrollierte Studien [Grossmann 2005].

Sensible Bereiche in der Kinderchirurgie sind die richtige Indikationsstellung sowie die Vermeidung von postoperativen Komplikationen und Rezidiveingriffe. Zu diesen Bereichen wurden anhand von zwei exemplarischen Studien im Bereich der Visceralchirurgie wichtige Aspekte analysiert um vorhandene Therapiekonzepte zu verbessern. Hierfür wurden einerseits in einer komplexen Abwägung der Indikationsstellung zur Fundoplikatio bei einem speziellen Patientegut patienten- bzw. elternorientierte Parameter ausgewertet und andererseits Kinder mit Rezidiveingriffen nach operativer Korrektur bei Morbus Hirschsprung hinsichtlich vermeidbarer Komplikationen evaluiert.

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4) Wyler von Ballmoos MC, Ware JH, Haring B. Clinical research quo vadis? Trends in reporting of clinical trials and observational study designs over two decades. J Clin Med Res. 2015:7(6):428-34

A Abwägung der Indikationsstellung unter Einbeziehung patienten-orientierter Parameter

Publikation: *Heinrich M, Kain A, Bergmann F, Schweinitz, D. Parents reported reduced symptoms and improved satisfaction after fundoplication and their perceptions were an important outcome measure. Acta Paediatr 2017;106(1):168-173*

Hintergrund: Die Therapie der gastro-ösophagealen Refuxkrankheit (GERD) bei Kindern ist primär konservativ. Die chirurgische Therapie mittels Fundoplikatio ist in chronisch rezidivierenden Krankheitsverläufen notwendig. Der Nachteil der chirurgischen Versorgung sind eine hohe Komplikations- und Rezidivrate insbesondere bei Kindern mit zusätzlichen Risikofaktoren, die eine klare Indikationsstellung zur operativen Versorgung erschweren.

Methodik und Patienten: In einer retrospektiven Studie untersuchten wir den Nutzen der Fundoplikatio bei Kindern aufgrund einer GERD mit Fokus auf den Langzeitverlauf von gastrointestinalen und pulmonalen Symptomen, die zur Indikation des operativen Engriffes geführt haben. Von 34 Patienten, die im Zeitraum von 2001 bis 2005 offen oder laparoskopisch an einer Fundoplikatio operiert wurden, konnten die klinischen Daten im Langzeitverlauf erhoben und ein aktuelles Interview mit den Eltern durchgeführt werden über die zur Operation geführten klinischen Symptome, deren postoperativen Verlauf sowie die Entwicklung der Ernährungssituation und die Zufriedenheit mit dem Eingriff.

Ergebnisse: Das durchschnittliche Follow-up lag bei 7,3 Jahre (± 1.7 Jahre). Die Patienten wurden in drei verschiedene Gruppen eingeteilt: Kinder mit neurologischer Beeinträchtigung (n=15), Kinder mit zusätzlicher gastrointestinaler Erkrankung und Kinder mit isolierter GERD ohne andere Begleitererkrankungen (n=12). 41% unserer Patienten hatten pulmonale

und gastrointestinale Symptome, die zur Fundoplikatio führten. Gehäuft trat dies bei Kindern mit neurologischen Begleiterkrankungen oder Kindern mit zusätzlichen gastrointestinalen Erkrankungen auf. Indikation zur Fundoplikation war in 75% eine therapierefraktäre Ösophagitis und eine Epitheldysplasie/-metaplasie in 50%. Ungefähr nur die Hälfte der Patienten wurde vor der Operation oral ernährt. Nur in der Gruppe mit neurologischen Begleiterkrankungen verblieben 11 Kinder mit einer Sondenernährung im Langzeitverlauf. Ein Re-Fundoplikatio war bei sieben Patienten notwendig. Zehn Patienten waren im Langzeitverlauf noch auf eine antazide medikamentöse Therapie angewiesen. Die Eltern berichteten, dass die initialen Refluxsymptome in 60% erfolgreich therapiert wurden, in 37% verbessert und in 3% unverändert blieben. Bei keinem der Patienten kam es zu einer Verschlechterung der initialen Symptome. Erbrechen konnte am erfolgreichsten in 82% durch die Fundoplikatio behandelt werden und refluxassoziierte Schmerzen in 78%. Pulmonale Symptome blieben oft unverändert, vor allem bei Kindern mit neurologischen Begleiterkrankungen. Neue Symptome traten am häufigsten bei Kindern mit neurologischen Begleiterkrankungen auf, in der Gesamtgruppe bei insgesamt zehn Patienten (Bolusereignisse, Dumping, Subileus, Tracheostoma, Schluckbeschwerden). 32 von 34 Eltern waren mit dem operativen Ergebnis zufrieden aufgrund der Verbesserung der refluxassoziierten Symptome und besseren Lebensqualität.

Zusammenfassung: Ein hoher Anteil der Eltern berichtet über eine Verbesserung der gastrointestinalen refluxassoziierten Symptome und einen hohen Level an Zufriedenheit im Langzeitverlauf nach Fundoplikatio. Die Einschätzung der Eltern bei GERD Symptomen sollte ein wichtigem Faktor sein in der Bewertung der Ergebnisse bezüglich der Effektivität der Fundoplikatio bei Kindern, insbesondere mit anderen Begleiterkrankungen.

Diese Studie untermauert die Bedeutung der Einschätzung der Eltern der postoperativen Entwicklung der zur Operation geführten Symptome und der Zufriedenheit in einem schwierigen Patientenkollektiv. Diese Daten helfen in der klinischen Routine auch in diesem sehr kleinen, speziellen Patientenkollektiv sinnvolle Therapiemepfehlungen formulieren zu können.

B Kritische Analyse von Rezidiveingriffen und deren Komplikationen bei Kindern mit Morbus Hirschsprung

Publikation: *Heinrich M, Häberle B, Schweinitz D, Stehr M. Re-operations for Hirschsprung´s disease: long-term complications. Eur J Ped Surg 2011;21:325-330*

Hintergrund: Bei einigen Patienten mit Morbus Hirschsprung ist die initiale chirurgische Versorgung nicht erfolgreich und die Patienten leiden an erneuten oder persistierenden Beschwerden. Es kann zu schweren Infektionen, intestinalen Obstruktionen, Stuhl-/Harninkontinenz, chronischen Bauchschmerzen oder Dystrophie kommen. Er gibt bisher nur wenig Literatur zur Empfehlung des diagnostischen und therapeutischen Vorgehens sowie zu Langzeitverläufen nach Re-Operationen bei Kindern mit Morbus Hirschsprung.

Methodik und Patienten: Wir verfolgten acht Fälle mit kompliziertem Morbus Hirschsprung, bei denen wiederholte chirurgische Eingriffe notwendig waren und dokumentierten die früheren Operationen, die histologischen Ergebnisse, die Indikationen zur Re-Operation, den postoperativen Verlauf und das klinische Ergebnis im Langzeitverlauf einschließlich Stuhlentleerung, Ernährungszustand und Harnentleerung.

Ergebnisse: Der Follow-up Zeitraum lag bei 3 bis 5,5 Jahre (Mean 4,4 Jahre). Die Indikationen für die Re-Operation waren ein blinder rektaler Pouch nach Duhamel-Operation (n=2), eine persistierende Aganglionose (n=4), eine langstreckige Stenose nach Rehbein-Operation (n=1) und eine Analstenose nach TERPT (transanal endorectal pull-through) (n=1). Bei 6 Patienten konnte als Re-Durchzugsoperation eine Duhamel-Operation erfolgen bei einer initiale Durchzugsoperation nach Duhamel (n=1) und nach Rehbein (n=5). Bei einem Patienten nach initialer Duhamel-Martin-Operation konnte aufgrund einer nicht mehr ausreichenden Gefäßstiellänge nur noch eine Rektumextirpation und endständiges Ileostoma

angelegt werden. Im Verlauf erreichten vier Patienten eine vollständige Stuhlkontinenz und ein Patient mit assoziierter Trisomie 21 erreichte lediglich eine partielle Stuhlkontinenz. Stuhlschmieren ein bis zwei Mal wöchentlich berichteten ein Patient mit totaler Aganglionose und ein Patient mit einer Fistel im kleinen Becken und vorhergehender subtotaler Kolektomie. Bei vier Patienten traten nach unserer Re-Operation Komplikationen auf: perianale Ulzerationen (n=2), wiederholte Botoxinjektionen bei Sphinkterachalasie (n=1), funktionelle Darmtransportstörung ohne Stenose (n=1). Bezüglich der Miktion berichteten im Langzeitverlauf sieben Patienten eine unauffällige Miktion ohne Harnverlust, ein Patient mit Trisomie 21 war nur teilweise harnkontinent und ein Patient berichtet selten über ein Urge-Inkontinenz.

Zusammenfassung: Somit verbesserten sich alle Patienten nach der weiteren chirurgischen Intervention. Teilweise war die Behebung der klinischen Symptome verzögert und eine Teil-Stuhlkontinenz oder Stuhlschmieren persistierten bei drei Patienten. Die meisten Komplikationen, die zu weiteren chirurgischen Operationen führten wären vermeidbar gewesen, insbesondere die Rest-Aganglionose. Daher sollte die primäre Versorgung von Kindern mit Morbus Hirschsprung unter hoher Sorgfalt und mit viel Erfahrung erfolgen um bei der Durchführung der initialen Operation die Komplikationen zu minimieren. Hierfür ist die Beachtung der Leitlinien und Empfehlungen der Fachgesellschaften Grundvoraussetzung für ein erfolgreiches Vorgehen.

Diese Studie unterstreicht, dass zur Vermeidung von späteren Komplikationen und Reeingriffe, ein sorgfältiges Einhalten von grundlegende diagnostischen und therapeutischen Schritten in der primären Versorgung von Kindern mit Morbus Hirschsprung und entsprechend erfahrene Kinderchirurgen in einem hoch qualifizierten interdisziplinären Team notwendig sind.

III. Optimierung der Schmerztherapie in der Kinderchirurgie

Dieser Aspekt des Habilitationsprojektes beschäftigte sich mit der Rationale, dass in der Kinderchirurgie im Alltag zu behandelnde Schmerzen häufig auftreten, meist handelt es sich um akute Schmerzen im Rahmen der Erkrankung oder eines Unfalls bzw. im perioperativen Verlauf. Der behandelnde Kinderchirurg steht in der Verantwortung diese akuten Schmerzen adäquat zu therapieren. Dies beinhaltet neben der analgetischen Therapie in der Notfallambulanz auch die postoperative Schmerztherapie und Analgosedierung bei schmerzhaften Maßnahmen. Verschiedene Studien konnten auch in Deutschland nachweisen, dass leider Kinder im Vergleich zu Erwachsenen hier meist nicht ausreichend behandelt sind mit oft unterdosierten Analgetika, zu seltenen Verabreichungen von Analgetika und oft schwächeren Analgetika [Bremerich 2001]. Eine suffiziente postoperative Analgesie hat neben den unmittelbaren Schmerzlinderung weitere positive Effekte auf den Heilungsverlauf durch eine Verbesserung der Wundheilung, eine bessere Sauerstoffversorgung und Durchblutung im Gewebe, Reduzierung der Stressantwort nach Gewebstrauma, zeitgerechte Mobilisierung und Prävention von chronischen Schmerzen [Taddio 1995, Akca 1999, Beilin 2003, Mitchell 2002]. Zusätzlich zu diesen Erkenntnissen ist bei der Entwicklung des nozizeptiven Systems von Neu- und Frühgeborenen die unterschiedliche Reifung des exzitatorischen und inhibitorischen Systems von entscheidender Bedeutung. Die Schmerzhemmung entwickelt sich deutlich später, als die aufsteigenden nozizeptiven Bahnen. Es besteht eine erniedrigte Schmerzschwelle und durch eine verstärkte Sensibilisierung kann rasche eine Hyperalgesie und Allodynie entstehen [Andrews 1994]. Vor diesem pathophysiologischen Hintergrund ist gerade bei Kindern eine qualifizierte Schmerztherapie notwendig. In der Literatur bestehen verschiedene Standards und Empfehlungen für die Akutschmerztherapie bei Kindern [Banos 2000], deren Umsetzung im Alltag zur Verbesserung der Qualität der Schmerztherapie ist allerdings schwierig.

Zur Verbesserung der Schmerztherapie bei Kindern wurde in unserer Klinik 2005 eine multidisziplinäre Arbeitsgruppe (Kinderschmerzgruppe) gegründet, deren Leitung von meiner Seite zusammen mit einer Vertreterin aus dem Qualitätsmanagement der Pflege aus dem Dr. von Haunerschen Kinderspital innehat. Treffen finden alle zwei Monate statt, die Teilnehmer setzen sich aus der Pflege, Kinderchirurgie, Pädiatrie, Kinderanästhesie, Physiotherapie und Pharmazie zusammen. Im weiteren Verlauf nahmen sowohl der Schmerzdienst der Anästhesie als auch der Psychosomatik teil. Zunächst wurde nach Festlegung der Organisation der Kinderschmerzgruppe ein Ablaufschema zur Bearbeitung von Projekten ausgearbeitet. Das erste Projekt der Kinderschmerzgruppe war die Einführung einer altersabhängigen Schmerzeinschätzung bei Kindern. Es wurden verschiedene validierte Schmerzskalen auf ihre Praktikabilität im Alltag getestet. Nach Festlegung der Skalen (KUSS-Skala und Smiley-Skala) wurde ein Schmerzschieber entwickelt. Außerdem wurde eine Prozeßbeschreibung für die Schmerzmessung und Integration der Schmerz-Dokumentation in den vorhandenen Kadex erarbeitet. Im Verlauf wurde auf die Bieri-Gesichterskala anstatt der Smiley-Skala gewechselt, wegen einer besseren Validierung und Aussagekraft. Im nächsten Schritt erfolgte die Ausarbeitung eines postoperativen Schmerztherapie-Managements. Hierfür wurden vorhandene Richtlinien und Empfehlungen auf die Bedürfnisse und Abläufe in unserer Klinik angepasst. Das Konzept zur postoperativen Schmerztherapie basiert auf drei Säulen: einer dem Ausmaß des chirurgischen Eingriffes angepasste Basisanalgesie, einer Bedarfsanalgesie je nach Schmerzscore und einer adjuvanten Schmerztherapie die den Schmerzcharakter und die Schmerzprophylaxe miteinbezieht [Till 2002]. Das Konzept wurde noch immer weiter überarbeitet und in ihrer Praktikabilität verbessert [Heinrich 2010].

Anhand der folgenden aufgeführten Studien wird einerseits die langfristige Etablierung und Optimierung der postoperativen Schmerztherapie bei Kindern im Alltag in einer prospektiven

Studie beschrieben und anderseits zwei Konzepten zur Analgosedierung durch den behandelnden Kinderchirurg in der (Notfall-) Ambulanz etabliert mit Überprüfung deren Effektivität und Sicherheit.

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A Langfristige Optimierung der postoperativen Schmerztherapie bei Kindern

Publikation: *Heinrich M, Mechea A, Hoffmann F. Improving postoperative pain management in children by providing regular training and an updated pain therapy concept. EJP 2016;20(4):586-93*

Hintergrund: Unbehandelte postoperative Schmerzen im Kindesalter können zu körperlichen Komplikationen, posttraumatischem Stress und langfristigen Verhaltensveränderungen führen. In Kinderkliniken wurden deshalb auf Basis aktueller Empfehlungen in den letzten Jahren zunehmend Behandlungskonzepte für die postoperative Schmerztherapie etabliert. Diese Protokolle beinhalten zuverlässige und altersentsprechende Methoden zur Schmerzmessung sowie zur effektiven postoperativen Schmerztherapie mit dem Ziel, Schmerzen in der postoperativen Phase zu minimieren und damit die Versorgungsqualität dieser Kinder zu optimieren. Obwohl viele Arbeiten zur Etablierung von Schmerztherapiekonzepten existieren, gibt es kaum Daten zur Effektivität und zum Langzeiteffekt deren Umsetzung. Wir untersuchten deshalb den Einfluss von Optimierungsstrategien eines bestehenden Schmerztherapiekonzepts sowie eines regelmäßigen Trainings aller Mitarbeiter auf die Langzeitqualität des postoperativen Schmerzmanagements.

Methodik und Patienten: Zu Beginn der Interventions-Studie wurde der IST-Zustand (Audit 1) analysiert. Anschließend wurden eine Optimierung des bestehenden Schmerztherapie-konzepts und drei Inhouse-Schulungen zur Schmerztherapie für Ärzte und Pflegepersonal durchgeführt. Im Rahmen eines zweiten Audit erfolgte nach drei Jahren eine Überprüfung des postoperativen Schmerzmanagements. Das Studiendesign ist in Abbildung 1 dargestellt.

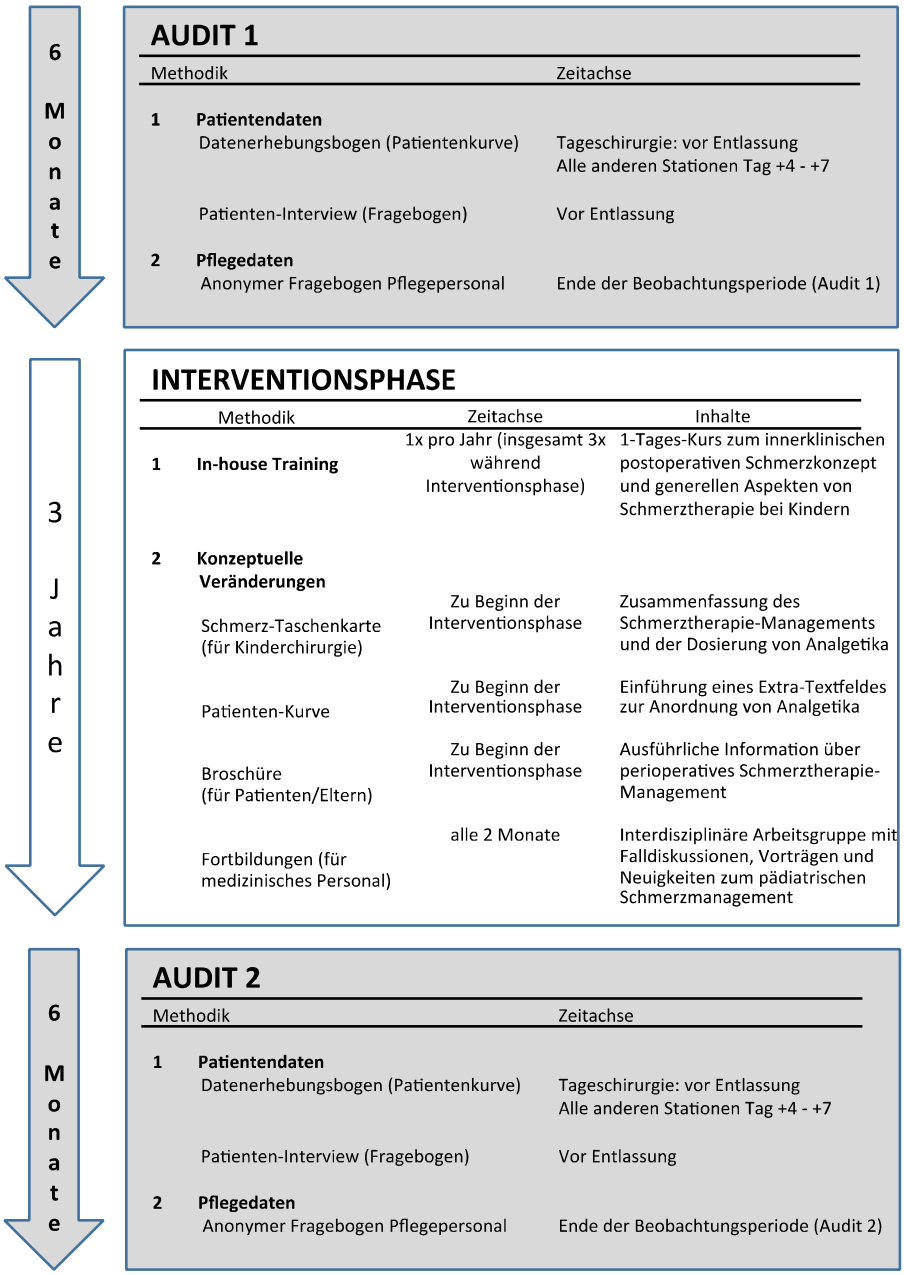

Abb. 1: Studiendesign der Interventionsstudie mit Audit 1, Interventionsphase und Audit 2

Als Auditinstrumente wurden Erhebungsbögen aus der Implementierung des Expertenstandards „Schmerzmanagement in der Pflege akuter Schmerzen“ (2003) und ein anonymer Fragebogen an das gesamte Pflegepersonal der kinderchirurgischen Klinik verwendet.

Ergebnisse: Unserer Analyse umfasste insgesamt 93 und 85 Patienten im initialen Audit 1 und im finalen Audit 2. Die Rücklaufquote der Fragebögen an das Pflegepersonal lag bei 83% (Audit 1) und 77% (Audit 2). Die Maßnahmen in der Intventionsphase hatten einen signifikanten Effekt im Bereich rechtzeitigen Verabreichung von Analgetika, der Überprüfung der Effektivität der analgetischen Therapie und der Anwendung von nicht-medikamentösen Schmerztherapie. Die Patienten berichteten insbesondere über eine schnellere Verabreichung von Analgetika bei akuten Schmerzen und über eine vermehrte Schmerzfreiheit sowie über eine suffizientere Information über den Umgang mit Schmerzen. Die Analgesie im Rahmen von schmerzhaften Maßnahmen im postoperativen Verlauf wurde zwar verbessert, war aber insgesamt noch unbefriedigend. Es erfolgte daher im Anschluss an diese Studie eine Überarbeitung und Verbesserung der Standards mit dem Angebot einer nicht-invasiven Applikation der Analgetika, höheren Variationsbreite der verschiedenen Analgosedierungen entsprechend dem Ausmaß der Maßnahmen und dem Alter des Patienten.

Zusammenfassung: Unsere Daten zeigen erstmalig, wie eine langfristige Umsetzung von postoperativer Schmerztherapie erreicht werden kann. Die von uns durchgeführten Interventionen mit wiederholten Fortbildungen und konzeptuellen Veränderungen konnte die Schmerztherapie in hohem Maße verbessern und das Bewusstsein für postoperative Schmerzen schärfen. Die Schulungen konnten erfolgreich in die schon vorhandenen Fortbildungsstrukturen eingebaut werden. Unsere Ergebnisse betonen die Wichtigkeit des interdisziplinären und kontinuierlichen Ansatzes beim Schmerzmanagement, um die vorhandenen Standards langfristig um zuzusetzen.

Diese Studie macht deutlich, dass eine Optimierung der klinischen Prozesse des Schmerzmanagements und regelmäßiges Training der Mitarbeiter notwendig sind um

eine langfristige Verbesserung der Versorgungsqualität von Kindern mit postoperativen Schmerzen zu erreichen.

B Etablierung verschiedener Methoden zur Analgosedierungen in der Kinderchirurgie

Publikation: *Heinrich M, Wetzstein V, Muensterer O. Till H. Conscious sedation: Off-label use of rectal S(+) ketamine and midazolam for wound dressing changes in paediatric heat injuries. Eur J Ped Surg 2004;14(4):235-9*

Heinrich M, Menzel, Hoffmann F, Berger M, Schweinitz D. Self-administered procedural analgesia using 50% Nitrous Oxide/50% Oxygen in the pediatric surgery emergency room: effectivness and limitations. Eur J Ped Surg 2015;25(3):250-6

Schmerzen treten im Alltag einer kinderchirurgischen Klinik häufig auf. Meist handelt es sich um akute Schmerzen im Rahmen der Erkrankung oder eines Unfalls bzw. im perioperativen Verlauf. Der behandelnde Kinderchirurg steht in der Verantwortung diese akuten Schmerzen adäquat zu therapieren und wünschenswert wären in einer kinderchirurgischen Klinik Standards für verschiedene Stufen einer Analgosedierung, angepasst an das Ausmaß der Intervention. Dies beinhaltet insbesondere Analgosedierungen, die der Kinderchirurg eigenständig ohne Anwesenheit eine Anästhesisten zur Therapie in der (Notfall-) Ambulanz einsetzen kann. Die Rahmenbedingungen für solche Analgosedierungen und die praktische Umsetzung im Alltag sowie die Effektivität und richtige Indikationsstellung wurde in den folgenden zwei Studien untersucht.

(1) Rektale Analgosedierung mit Midazolam und S(+)-Ketamin für ambulante chirurgische Eingriffe bei Kindern

Heinrich M, Wetzstein V, Muensterer O. Till H. Conscious sedation: Off-label use of rectal S(+) ketamine and midazolam for wound dressing changes in paediatric heat injuries. Eur J Ped Surg 2004;14(4):235-9

Hintergrund: Verbandswechsel bei Verbrennungen und Verbrühungen bedeuten für den Patienten wiederholte schmerzhafte und angsteinflössende Eingriffe in kurzen Zeitabständen. Eine sichere, adäquate und leicht zu applizierende Analgesie und Sedierung ist wünschenswert. Das Ziel dieser Studie war die Evaluierung von rektal verabreichten Ketamin-S(+) und Midazolam für wiederholte Verbandswechsel bei Kindern durch den behandelnden Kinderchirurgen.

Methodik und Patienten: Im Rahmen einer prospektiven Studie wurden 47 Verbandswechsel bei 30 Kindern mit I-IIa° Verbrennungen oder Verbrühungen untersucht. Ausgewertet wurden die Vitalparameter, Nebenwirkungen, Komplikationen, Anxiolyse und Analgesie während der Eingriffe und des anschließenden zweistündigen Überwachungszeitraumes. Die Patienten wurden anhand eines Entlassungs-Scores (Aldrete Discharge Score, ASS) und einer altersentsprechenden Schmerzeinschätzung in regelmäßigen Abständen beurteilt. Vor der Entlassung wurde die Zufriedenheit der Eltern mit einem Fragebogen evaluiert.

Ergebnisse: Eine adäquate Sedierung und Analgesie konnte bei 44 Eingriffen erreicht werden (94%). Es traten keine Komplikationen, insbesondere keine Beeinträchtigungen der Atemwege oder des kardiovaskulären Systems auf. Der Entlassungs-Score (ASS) zeigte schon nach 30 Minuten nach dem Eingriff bei allen Patienten eine Entlassungsfähigkeit an. Die Eltern waren insgesamt sehr zufrieden mit dem Ablauf der Verbandswechsel. Alle

Kinder, die alt genug waren Angaben zu machen, gaben eine anterograde Amnesie für die Dauer des Eingriffes an.

Zusammenfassung: Eine „conscious sedation“ mit rektaler Medikamentenapplikation von Ketamin-S(+) und Midazolam ermöglicht eine sichere und schmerzfreie Durchführung des Verbandswechsel nach bei Verbrennungen und Verbrühungen bei Kinder mit kleinen, oberflächlichen Wunden.

(2) Inhalative Analgosedierung mit einem $N_20/0_2$ (50:50)-Gemisch in der kinderchirurgischen Notfallambulanz

Heinrich M, Menzel, Hoffmann F, Berger M, Schweinitz D. Self-administered procedural analgesia using 50% Nitrous Oxide/50% Oxygen in the pediatric surgery emergency room: effectivness and limitations. Eur J Ped Surg 2015;25(3):250-6

Hintergrund: Kleine chirurgische Eingriffe in der Notfallambulanz sind bei Kindern oft eine große Herausforderung aufgrund der mangelnden Kooperation. Eine Sedierung und Analgesie wäre oft hilfreich und erforderlich. Die Applikation der dafür notwendigen Medikamente sind für die Kinder oft unangenehm (nasale oder rektale Gabe) oder schmerzhaft (i.v. Gabe). Die Inhalation von $N_20/0_2$ als 50:50-Gemisch könnte eine sinnvolle Alternative sein, insbesondere in der Notfallambulanz aufgrund der nicht erforderlichen Nüchternheit und der selbstverabreichenden Inhalation.

Methodik und Patienten: In unserer Studie erfolgte eine prospektive Evaluation der Sedierung und Analgesie bei kleinen notfallmäßigen chirurgischen Eingriffen durch $N_20/0_2$ (50:50) Inhalation über einen Zeitraum von 2,5 Jahre in unserer kinderchirurgischen Notfallambulanz.

Indikationen für diese Analgosedierung waren kleinere schmerzhafte Interventionen, Lokalanästhesie bei Wundversorgungen oder Leitungsanästhesie (Oberst-Anästhesie) zur Wundversorgung oder Reposition bei Fingerverletzungen. Die Diagnose, Art der Operation, Inhalationszeit, Nebenwirkungen, periinterventioneller Schmerzscores und die Reaktion des Kindes auf die Maßnahme wurden untersucht.

Ergebnisse: 210 Kindern (Alter 2,7 bis 16,5 Jahre, Mittelwert 9,0 Jahre) wurden in die Studie eingeschlossen. Drei Behandlungen mussten aufgrund von mangelnder Compliance, Übelkeit oder Schwindel abgebrochen werden. Es traten keine anderen Nebenwirkungen oder Komplikationen auf. Während der chirurgischen Maßnahme waren 80,5% der Patienten schmerzfrei und 81,9% waren entspannt und ruhig. Bei Injektionen einer Oberst-Anästhesie oder Repositionen wurde im Vergleich zu den anderen Eingriffen eine höhere Rate an insuffizienter Schmerztherapie beobachtet. Bei diesen Patienten zeigten sich ein erhöhter Schmerzscore und eine deutlichere Schmerzreaktion in der Beobachtung mit Weinen, Abwehrreaktion oder Festhalten während der Maßnahme.

Zusammenfassung: Somit lässt sich die Anwendung von $N_20/0_2$ (50:50) Inhalation für kleiner chirurgische Eingriffe bei Kindern in der Notfallambulanz sicher und mit adäquater Schmerztherapie in den meisten Fällen einsetzen. Der große Benefit ist die nicht erforderliche Nüchternheit, die gute Anxiolyse bei einem Minimum an Sedierung sowie ein kooperativer Patient. Limitationen sind eine nicht zufriedenstellende Analgesie in einigen Fällen, so dass die Indikationsstellung korrekt gestellt und immer wieder überdacht werden sollte. Auch wenn in unsere Studie keine schweren Nebenwirkungen aufgetreten sind, sollten die Richtlinien für minimale Sedierungen und Analgesie sowie die personellen und technischen Voraussetzungen immer eingehalten werden.

Diese beiden Studien tragen dazu bei alltagstauglich eine Implementierung von Analgosedierungen in der Kinderchirurgie zu erreichen um auch bei kleineren schmerzhaften Maßnahmen bei Kindern eine adäquate Schmerzkontrolle unter sicheren Bedingungen zu schaffen.

IV. Optimierung diagnostischer Therapiekonzepte in der Kinderurologie zur Vermeidung von Strahlenbelastung

Dieser Aspekt des Habilitationsprojektes beschäftigte sich mit der Rationale, dass in Kinderchirurgie oft empirische und individuelle Therapiekonzepte existieren, sowie teilweise nicht in klinischen Studien suffizient überprüfte Aussagen zur notwendigen Diagnostik in der aktuellen Literatur oder Empfehlungen vorhanden sind. Betrifft dies Untersuchungen, die eine Strahlenbelastung zur Folge haben, ist eine Aufdeckung von unnötigen Untersuchungen sehr wichtig und trägt zum Schutze des Patienten und Senkung der Morbidität bei. Die Strahlenschutzkomission empfiehlt die rechtfertigende Indikation für die Anwendung von ionisierender Strahlung bei Kindern besonders streng zu stellen aufgrund der Tatsache, daß das Kind besonders stahlenempfindlich ist und ein höheres Strahlenrisiko als Erwachsene hat [Empfehlung der Strahleschutzkomission 2006]. Eine Aufarbeitung der Rechtfertigung einer routinemäßigen invasiven, mit Röntgenstrahlen verbundenen Diagnostik bei Kindern ist daher notwendig.

Anhand von zwei exemplarischen Studien im Bereich der Kinderurologie werden die Möglichkeiten zur Optimierung von Therapiekonzepten aufgezeigt unter dem Aspekt der Vermeidung von Strahlenbelastung durch eine systematische Aufarbeitung der Daten zu dem diagnostischen Vorgehen bzw. postoperativen Langzeitverläufen.

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A Rechtfertigung einer routinemäßigen invasiven Diagnostik zum Ausschluss eines vesicorenalen Reflux (VUR) bei Kindern mit Ureterabgangsstenose (UAST)

Publikation: *Hubertus J, Plieninger S, Martinovic V, Heinrich M, Schuster T, Bürst M, Schroeder A, Beetz R, Dietz HG, Stehr M. Children and adolescents with ureteropelvic junction obstruction: is an additional voiding cystourethrogram necessary? Results of a multicenter study. World J Urol 2013;31(3):683-687*

Hintergrund: Die Koinzidenz der Ureterabgangsstenose (UAST) und dem vesikoureteralen Reflux (VUR) wird in der Literatur mit 14 bis 18% angegeben. Aus diesem Grund wird in verschiedenen Leitlinien und Empfehlungen ein Röntgen-Miktionszystouretherogram (MCU) zur Identifikation eines VUR in der frühen Diagnostik als notwendig angeben. Anhand eine Multizenterstudie soll diese Inzidenz überprüft werden und eindeutig die Notwendigkeit einer invasiven strahlenbelastenden Untersuchung festgelegt werden.

Methodik und Patienten: Die Unterlagen von 266 Patienten (69 weiblich, 197 männlich) mit UAST wurden retrospektiv ausgewertet. Erfasst wurden Daten zu den klinischen Symptomen, Ergebnisse des prä- und postnatalen Sonographie des Harntraktes, MCU und MAG3 (^{99m}Tc-Mercapto-acetyltriglycin) Nierenszintigraphie. Die Ergebnisse wurden korreliert mit der Koinzidenz eines VUR.

Ergebnisse: 178 Patienten (67%) erhielten ein MCU in der diagnostischen Abklärung. Bei 13 Patienten fand sich ein VUR mit der Koinzidenz von 7,3%. Bei nachgewiesenem VUR fand sich eine prädiktiver Wert für das weibliche Geschlecht, eine sonographisch nachgewiesenen Harnleiterdilatation retrovesikal und rezidivierende Harnwegsinfektionen. Es bestand keine Korrelation zwischen dem Nachweis eines VUR und dem Schweregrad der Hydronephrose.

Zusammenfassung: Unsere Daten rechtfertigen mit einer niedrigen Koinzidenz des VUR bei UAST im Kindesalter keine routinemäßige Durchführung eines invasiven und Stahlen belastenden MCU. Eine sonographische retrovesikale Harnleiterdilatation oder wiederholte Harnwegsinfektionen haben allerdings einen prädiktiven Wert für einen begleitenden VUR.

Diese Studie hebt hervor, dass vorhandene Empfehlungen zur Diagnostik immer wieder auf deren Gültigkeit reevaluiert werden müssen insbesondere um routinemäßige invasive und strahlenbelastende Diagnostik zu hinterfragen.

B Optimierung der postoperativen Verlaufskontrolle mittels MAG3 Nierenszintigraphie nach Korrektur einer einseitigen Ureterabgangsstenose (UAST) im Kindesalter

Publikation: *Heinrich M, Becker K, Pfluger T, Dietz HG. Split renal function outcomes one year after paediatric pyeloplasty for unilateral ureteropelvic junction obstruction. (Zur Veröffentlichung eingereicht bei J Pediatr Urol)*

Hintergrund: Die operative Korrektur der UAST bei Kindern hat eine hohe Erfolgsrate von 98-91%. Zur postoperativen Verlaufskontrolle werden in der Regel neben dem Ultraschall der ableitenden Harnwege eine MAG3 (^{99m}Tc-Mercapto-acetyltriglycin) Nierenszintigraphie eingesetzt. Die MAG3 Nierenszintigraphie dokumentiert den Erfolg der Pyeloplastik durch Nachweis der Partialfunktion der betroffenen Niere und den Abflussverhältnissen aus dem Nierenbecken im Vergleich zur präoperativen Untersuchung. Der optimale Zeitpunkt zur Durchführung dieser invasiven und strahlenbelastenden Untersuchung wird in der Literatur kontrovers diskutiert und sehr unterschiedlich in den verschiedenen Protokollen gehandhabt mit sehr variablen Zeitabständen sowie teils routinemäßig mehrfachen postoperativen Kontrollen. Zur Evaluierung der postoperativen Partialfunktion ein Jahr nach Pyeloplastik bei unilateraler UAST in der MAG3 Nierenszintigraphie und Untersuchung von präoperativen Einflussfaktoren auf den Verlauf der Nierenfunktion sowie Diskussion des optimalen Follow-up erfolgte eine retrospektive Analyse unseres Patientenkollektivs.

Methodik und Patienten: Wir führten eine retrospektive Datenanalyse bei Kindern mit isolierter unilateraler UAST mit einer Pyeloplastik nach Anderson-Hynes im Zeitraum von 2000 bis 2015 durch mit folgenden Ausschlusskriterien: funktionelle Einzelniere, Harnwegsinfektionen, andere urogenitale Fehlbildungen wie zum Beispiel ein assoziierter vesikoureteraler Reflux oder eine Doppelobstruktion mit Megaureter. Die Ergebnisse der

präoperativen und ein Jahr postoperativen MAG3 Nierenszintigraphie wurden bezüglich der Partialfunktion und Drainage ausgewertet. Anhand der präoperativen Partialfunktion (PF) wurden die Patienten in vier Gruppen eingeteilt: Gruppe I (PF > 40%), Gruppe II (PF 31–40%), Gruppe III (PF 21–30%), Gruppe IV (PF ≤ 20%). Der Grad der Hydronephrose (Society of Fetal Urology Grading System (SFU)) und der anterioposterio (AP) Durchmesser des Nierenbeckens in der sonographischen Untersuchung präoperativ sowie drei, sechs und 12 Monate postoperativ wurden ebenfalls erfasst. Außerdem wurden die präoperativen klinischen Daten sowie postoperative Komplikationen ausgewertet.

Ergebnisse: 118 Patienten konnte in die Studie eingeschlossen werden. Das mittlere Alter bei der Operation lag bei 1,8 Jahre (Range: 1 Monat bis 15,4 Jahre). In der postoperativen MAG3 Nierenszintigraphie nach durchschnittlich 14,4 Monaten (Range: 10–19 Monaten) zeigte sich bei 116 Patienten (98,3%) eine Verbesserung der Drainage mit einem mittleren Anstieg von 53%. Die postoperative Partialfunktion der betroffenen Niere verblieb stabil (Variation von ± 5%) bei 66 Patienten (56%), verbesserte sich bei 49 Patienten (41,5%) und verschlechterte sich bei drei Patienten (2,5%). Ein Anstieg der Partialfunktion war signifikant häufiger in der Gruppe II. Die präoperative Partialfunktion, Ausmaß der präoperativen Obstruktion oder das Alter bei Operation hatten keinen Einfluss auf die Verbesserung der postoperativen Partialfunktion. Komplikationen traten mit einem Urinom/Urinleak in 1,7% (n=2) auf und eine Re-Pyeloplastik musste bei einem Patienten (0,8%) erfolgen. In den sonographischen Verlaufskontrollen zeigte sich bei allen bis auf einen Patienten eine rückläufige Hydronephrose, die mit einer Verbesserung der Drainage ohne Hinweis auf eine verbliebene Obstruktion in der MAG3 Nierenszintigraphie nach einem Jahre korrelierte. Nur bei einem Patient stelle sich in der Sonographie nach drei Monaten eine Zunahme der Hydronephrose dar und in der vorgezogenen MAG3 Nierenszintigraphie bestätigte sich eine Obstruktion, so dass eine Re-Pyelopastik notwendig wurde.

Zusammenfassung: Die postoperative Partialfunktion konnte bei 97,5% der Patienten mit unilateraler UAST nach Pyeloplastik erhalten werden, mit einer Verbesserung der Partialfunktion in 41,5%. Das Risiko für einen Verlust der Nierenfunktion ist sehr gering. Der optimale Zeitpunkt für die Kontrolle der MAG3 Nierenszintigraphie nach Pyeolplastik lässt sich hier nicht eindeutig klären. Aufgrund unserer Daten scheint eine Kontrolle nach einem Jahr sinnvoll, da in den ersten Monaten eine sonographische Kontrolle ausreichend Information über den postoperativen Erfolg gibt. Routinemäßige wiederholte Kontrollen der invasiven stahlenbelastenden MAG3 Nierenszintigraphie sind unnötig.

Diese Studie betont die Notwendigkeit das postoperative Follow-up mit invasiven strahlenbelastenden Untersuchungen kritisch zu beleuchten und auf ein medizinisch vertretbares Minimum zu reduzieren basierend auf Ergebnissen einer patientenorientierten klinischen Forschung.

Anhang

Aktualisiertes Verzeichnis wissenschaftlicher Abhandlungen

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SURGICAL ENDOSCOPY
and Other Interventional Techniques

Comparison of different training models for laparoscopic surgery in neonates and small infants

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Abstract
Background: Minimally invasive surgery in small children and infants requires special skills and training. This experimental study compares the efficiency of an *in vitro* pelvic trainer (PT) and an a *in vivo* animal model (AM).
Methods: For this study, 12 residents were prospectively randomized into two groups. Initially, all had to pass a basic skill assessment (3 tasks). Then endoscopic small bowel biopsy was performed (8 times) either with the *in vitro* PT (group A) or the *in vivo* AM (group B). Finally, all had to demonstrate this procedure in the *in vivo* AM and repeat the basic skill assessment. A quality index (complications, suture, biopsy) was evaluated.
Results: Initially, there was no difference between the two groups. Interestingly, the mean regression gradient of the index for the *in vitro* PT (group A) was significantly better than for the *in vivo* AM (group B). In the final *in vivo* operation, however, the mean index for the *in vitro* PT (group A) worsened significantly, whereas it increased for the *in vivo* AM (group B) ($p = 0.037$).
Conclusion: Adequate training for an isolated mechanical task such as gut biopsy can be supplied using a pelvic trainer or animal model with similar effects. However *in vivo* performance of the same task requires secondary surgical skills, which are conveyed during live training with greater success. Consequently, stepwise teaching with both modules seems reasonable before these procedures are approached in neonates or small children.

Key words: Children — Learning curve — Minimally invasive surgery

Advanced minimally invasive procedure's for small children are increasing. However, to embrace these techniques and to ensure their feasibility, safety, and efficacy for pediatric patients, adequate training seems essential. Although the operating room is the predominant venue for the acquisition of primary technical skills by surgeons, this mechanism may not apply as well to pediatric surgery because the number of patients is limited. Consequently, highly specialized skills and techniques need to be trained outside the operating room.

From general surgery it is known that laparoscopic surgical training is multifaceted and poses a new obstacle to skill acquisition, because significant experience is required before competency is achieved [5, 10, 14]. Several models for learning technical skills outside the operating room are available inanimate models (skills board within a training box), *in vivo* animal models, and virtual reality simulators [3, 8, 12, 13]. The advantages and disadvantages of these different teaching models for minimally invasive techniques in pediatric surgery have not been investigated. In a previous study, the authors demonstrated that for endosurgical procedures in newborn babies, a rabbit animal model simulates the anatomic situation more accurately because the rabbit's body weight and limited dimensions compare closely with those of neonates [16]. The purpose of this study was to evaluate and compare two teaching tools for laparoscopic procedures in pediatric surgery: an inanimate pelvic trainer model and a live animal model.

Materials and methods

The inclusion criteria specified residents in their second, third, or fourth year of training in pediatric surgery who had performed fewer than 20 minimally invasive operations by themselves. The residents who met these criteria were prospectively randomized in to two groups for training in gut biopsy using a neonatal model. At baseline in the participants had to take a test on certain laparoscopic skills including instrument handling, video eye-to-hand coordination, and basic knotting techniques (basic skill assessment). A video demonstrating the operation step-by-step was shown to every participant.

Every resident trained for laparoscopic gut biopsy eight times in a period of 2 weeks. The first group trained with an *in vitro* pelvic trainer model (group A) and the second group trained with an *in vivo* rabbit model (group B). A final test was taken by both groups using the *in vivo* rabbit model temporally separated from the eight training operations. This final test was intended to create a stress situation in

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which all the participants felt as though they were doing the gut biopsy in a patient. At the conclusion of the study, the basic skill assessment was repeated.

Basic skill assessment

At baseline and at the conclusion of the study, the residents were tested on an inanimate trainer. The tasks included a needle transfer drill, a box drill, and a suture foam drill. The needle transfer involved using two graspers to transfer as many curved needles as possible from one cup to another within 3 min. The box drill focused on the time required to open a matchbox, pickout one match, close the matchbox, and then put the match back into the box. The suture foam drill involved performing an intracorporeal suture of three knots within 12 min. These drills were popular training methods used in different skill center curricula or studies [4, 15].

Pelvic trainer model

A standard pelvic trainer was rebuilt. The space was adapted to the previously measured exact dimension of the peritoneal cavity of the New Zealand white rabbit and a soft surface was applied. A skill board with the water-filled gut of a sacrificed rabbit with a soft surface and a small interior was placed in the pelvic trainer. The distance between the surface of the pelvic trainer and the bowel was made to have the same range as in the rabbit model during pneumoperitoneum. The cannula was fixed with sutures, and the target bowel was placed by the supervisor for every single operation.

Live rabbit model

New Zealand white rabbits with a mean body weight of 2.23 kg (range, 1.87–2.77 kg) were used. A general anesthesia, a central venous line, and a tracheotomy were performed for the procedures. The cannula was placed by the supervisor, and a pneumoperitoneum was established. The cannula was fixed with sutures, and the target bowel was placed by the supervisor for every single operation at the same distance. The National Research Council's guide for the care and use of laboratory animals was followed.

Laparoscopic gut biopsy

The participants handled 3-mm instruments. The 5-mm scope was operated in every operation by the same person, which was not the team supervisor of the study, who did and not participate in the preparation or evaluation of this study. A gut biopsy of the serosa and muscularis was performed, and the defect was sutured with a 6/0 prolene thread using the intracorporael technique with a single suture and three knots.

Data analysis

The results of the baseline basic skill assessment (the number of transferred needles, the time for the box drill, and the mean time for one suture) were compared with the second assessment of each participant. For evaluating the quality of the gut biopsy and the personal skill, an index was created including the area, complication, suture, and biopsy (Table 1). This index was created in conjunction with experts in minimally invasive surgery. The completeness of the factors for judging the quality of suture and the complications of a gut biopsy, including the rating of each factor, was carefully elaborated. The rating system with different scoring represents live-time conditions. The best possible score is 100.

At the conclusion of the study, the index of each operation was evaluated with the video record. For validation, three operations of each participant were scored and compared with the indexes of two different independent experienced pediatric surgeons, and the result was compared with the index scoring from the study.

Table 1. Index for evaluating the quality of the gut biopsy and the personal skill of each operation of every participant, with a best possible score of 100

		Best score (points)
Complication		
Perforation	No (20)	
	Yes (0)	20
Concomitant injury	No (8)	
	Yes (0)	8
Good tissue handling	Yes (8)	
	Tear (4)	
	No (0)	8
Suture		
Suture removal	No (8)	
	Yes (0)	8
Fixed suture	Yes (8)	
	No (0)	8
Needle grasping	0–2x (8)	
	3–4x (4)	
	>5x (0)	8
Suture time	6 min (20)	
	7–10 min (10)	
	>10 min (0)	20
Biopsy		
Successful	Yes (20)	
	No (0)	20
		100

Statistical analysis

The baseline and final basic skill assessment were compared between the groups and within each group using with an *f*-test. A student's *t*-test were used to analyze the index between the two groups and to compare the gradient of linear regression of the index. The index scores in the study were compared with the indexs of the two test surgeons using the Mann – Whitney *U* test.

Results

The 12 residents included in the study were prospectively randomized into two groups.

Basic skill assessments

Residents were evaluated for their laparoscopic surgical experience before participating in the study. The mean results per individual task were not significantly different between the two groups at baseline. The mean results for the task decreased in both groups in the second assessment, with a significant difference for the suture drill in group A and for the box drill in group B. There was no significant difference between the two groups (Table 2).

Index

The improvement of the index was better in group A than in group B. The comparison of the indexes for operation's 1 and 8 showed no significant difference between the both groups. The mean regression gradient of the index for group A was significantly better than for group B (Figs. 1 and 2). In the final gut biopsy test, the mean index of group B increased, but the mean index of group A decreased. The difference was significant

Table 2. Comparison of the basic skill assessment at baseline and at the conclusion of the study between the two groups (no significant difference) and within each group

	Baseline	Conclusion	Difference
Pelvic trainer (group A)			
Needle transfer	7.33 ± 7.0	13.00 ± 12.5	5.67 ± 5.0
Box drill	1.92 ± 1.65	1.15 ± 0.84	0.77 ± 0.48
Suture foam drill	6.34 ± 6.08	2.58 ± 2.46[a]	3.76 ± 3.57
Rabbit-Model group (B)			
Needle transfer	11.83 ± 13.0	15.75 ± 15.5	3.25 ± 3.0
Box drill	1.92 ± 2.13	0.93 ± 0.96[a]	1.08 ± 1.18
Suture foam drill	4.18 ± 3.44	3.79 ± 3.37	0.05 ± 0.1

[a] $p < 0.05$

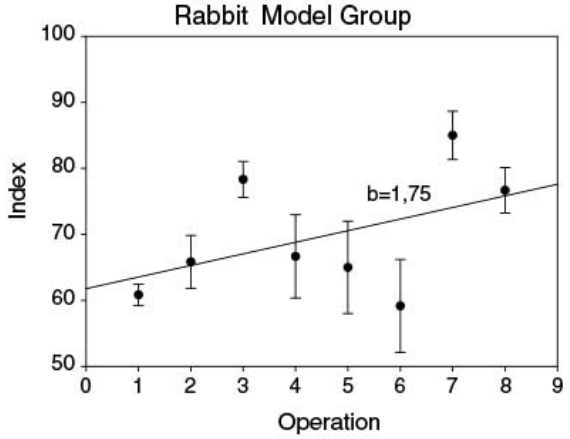

Fig. 1. Gradient of the linear regression of the index from participants in the rabbit model group who have performed a laparoscopic gut biopsy eight times.

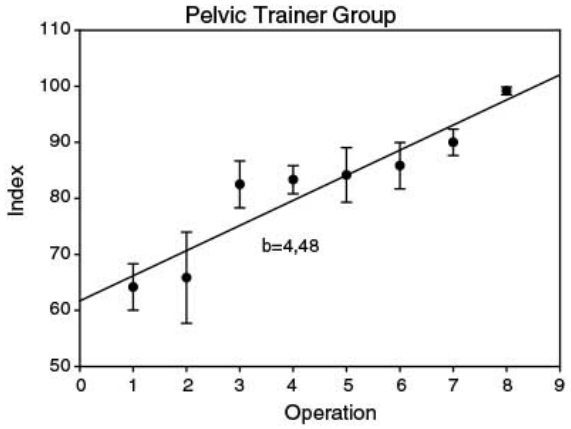

Fig. 2. Gradient of the linear regression of the index from participants in the pelvic trainer group who have performed a laparoscopic gut biopsy eight times.

($p = 0.037$) (Fig. 3). There was no significant difference in the results from the evaluation of the index for the three operations between any of the participants in the study and the two test surgeon. Therefore, this index is an objective instrument for judging the quality of the gut biopsy.

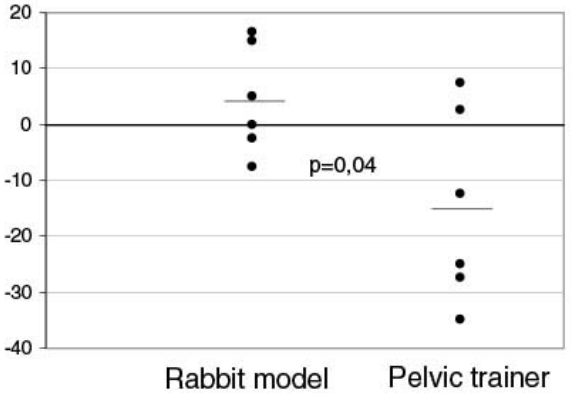

Fig. 3. Changes in the index (0–100 points) between the final gut biopsy and the last test gut biopsy in both groups.

Discussion

Minimally invasive surgical training programs have developed a curriculum in which surgeons learn basic skills such as two-hand coordination, suturing, and knot-tying. Several authors agree that suturing and knot-tying skills should be practiced in inanimate models [7, 17] and even supporters of animal models acknowledge that these particular skills can be learned using this approach [1]. Inanimate training is simple, inexpensive, and portable.

Basic laparoscopic skills have been evaluated at different times during an inanimate training course, and it was found overall that these skills improved significantly, as compared with observations at baseline [11]. We know that some minimally invasive surgical procedures have a longer learning curve, as evidenced by conversion rates, operative time's and the complication rates [2, 6]. Appropriate training and supervision affect

the learning curve. Nevertheless, pediatric endoscopic surgery not only requires appropriate highly specialized technical skills, but the number of patients also is usually small and additional training is essential to improve the learning curve. Do we need animal models, or is the effort of training with an inanimate model to enhance technical proficiency for pediatric endoscopic surgery sufficient?

The results of the basic skill assessment in this study confirm the performance in adult research [9]. Both study groups improved significantly in one of three tasks. No difference in basic skills improvement was observed between the *in vitro* pelvic trainer and the *in vivo* rabbit model. The learning curve represented as the regression gradient of the trend in the index was significantly better in the pelvic trainer group. In the final test, the index of the pelvic trainer group decreased significantly to the level of the first training. Therefore, the better training effect of the pelvic trainer was rendered useless by changing to the *in situ* model. Group B had a better training effect for the basic techniques of the gut biopsy, but could not transfer this knowledge and skills to the live operation. The reasons seem to be the dimension of the live abdominal cavity, resulting in increasing concomitant injuries and suture time. The limited abdominal dimension of the rabbit and the live operation seem to influence the inanimate-trained participant. This means that in the change to actual patients after inanimate training, the surgeon is not protected from complications, especially when applying highly specialized technical skills in limited space, as in newborn surgery. Furthermore, specific live intraoperative conditions are an important component in the teaching of pediatric endoscopic techniques before these procedures are approached in neonates or small children.

In conclusion, endosurgical techniques in pediatric surgery can be improved by several training models, and the pelvic trainer model teaches basic techniques adequately. On the other hand, an animal model conveys specific intraoperative conditions mandatory for advanced pediatric endosurgery. Thus, a stepwise teaching process seems optimal before safe and efficient operations are offered to infants or smaller children. Perhaps this study can help to initiate a training center for minimally invasive operations in pediatric surgery with an adapted pelvic trainer and animal model.

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Research Article

Evaluation of a Pilot Project to Introduce Simulation-Based Team Training to Pediatric Surgery Trauma Room Care

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Introduction. Several studies in pediatric trauma care have demonstrated substantial deficits in both prehospital and emergency department management. *Methods*. In February 2015 the PAEDSIM collaborative conducted a one and a half day interdisciplinary, simulation based team-training course in a simulated pediatric emergency department. 14 physicians from the medical fields of pediatric surgery, pediatric intensive care and emergency medicine, and anesthesia participated, as well as four pediatric nurses. After a theoretical introduction and familiarization with the simulator, course attendees alternately participated in six simulation scenarios and debriefings. Each scenario incorporated elements of pediatric trauma management as well as Crew Resource Management (CRM) educational objectives. Participants completed anonymous pre- and postcourse questionnaires and rated the course itself as well as their own medical qualification and knowledge of CRM. *Results*. Participants found the course very realistic and selected scenarios highly relevant to their daily work. They reported a feeling of improved medical and nontechnical skills as well as no uncomfortable feeling during scenarios or debriefings. *Conclusion*. To our knowledge this pilot-project represents the first successful implementation of a simulation-based team-training course focused on pediatric trauma care in German-speaking countries with good acceptance.

1. Introduction

Trauma is the most common cause of death in children aged one year and older and the main cause of permanent disabilities [1]. The treatment of injuries and life-threatening emergencies in children is a major cognitive challenge and an emotional burden for the treatment teams providing care in the trauma room, even in a Level 1 trauma center for children. Various studies have been able to identify massive deficiencies preclinically as well as in the pediatric surgery trauma room and in pediatric trauma care [2]. The deficits described in emergency care are found not only in the medical-specialty area, but also in the area of the so-called nontechnical skills. These nonmedical errors account for approximately 70 percent of errors according to a report published in 2000 titled "To Err is Human" [3].

Therefore, team-training concepts are increasingly being implemented in many high-risk medical fields as a tool to ensure that interdisciplinary medical care teams are best prepared for emergency situations. These courses allow medical professionals to receive training and some medical-specialty skills and learn team-oriented and behavior-oriented techniques [4].

The European division of the WHO showed that high-quality trauma care can reduce the mortality rate following trauma by up to 30 percent [1]. Numerous studies have been able to demonstrate that time delays in trauma care occur

when activities are not carried out in coordinated succession [2, 5, 6].

Until now, team trainings have not been available focused on pediatric trauma room care for children with major trauma in German speaking countries.

The objective of the pilot project described in this study was, therefore, to establish interdisciplinary simulation-based team training in Germany as a tool to improve the care of trauma patients in the pediatric surgery trauma room.

2. Methods

The first interdisciplinary, simulation-based team training in the pediatric surgery trauma room was held in Tuebingen. The training included 14 medical doctors and 4 nurses from the medical fields of pediatric surgery, pediatric intensive care and emergency medicine, and anesthesia. All of the medical doctors were attending physicians of pediatric surgery, pediatrics, and anesthesia having more than 10 years of practice each. Two weeks before the course started, for theoretical preparation the participants received the guidelines for emergency pediatric care based on the ERC guidelines from the European Resuscitation Council 2010 (ERC). The faculty consisted of eight CRM-trained instructors from the fields of pediatric intensive care, pediatric surgery, anesthesia, and pediatric emergency medicine. Training was held in a mock trauma room in the Tuebingen Patient Safety and Simulation Center (TüPASS) of the University Hospital Tuebingen.

The course lasted 1.5 days. On the first day of the course, the participants received three hours of theoretical introduction to the topics "Trauma Room Management in Pediatric Patients" and "Errors and Patient Safety in Pediatric Emergency Care." On the second day, participants then had a one-hour introduction to get familiarized with the simulator and the training environment. Also, skill stations focused on airway management and IO access were set up. Next, the training went through six scenarios exclusively from the field of pediatric surgery trauma room care (Table 1). The training goals were adapted to each scenario. Attention was given to ensure that all steps of the diagnostic and therapeutic algorithm of the European Pediatric Life Support (EPLS) [7] or Advanced Trauma Life Support (ATLS) courses [8] had a thematic focus in the scenarios. Here the patient was evaluated using the graduated approach following the ABCD scheme (where A = airway, B = breathing, C = circulation, and D = disability). The scenarios with each of the key medical areas and the CRM learning objectives are illustrated in Table 1. The time schedule of each training sequence was 15 minutes for the scenario with subsequently a 45-minute video-based debriefing for the participants. Therefore a higher weighting was focused on the debriefing allowing sufficient time for complete discussion of the key aspects. It was led by a two-person, interdisciplinary and multiprofessional instructor team. The ratio of medical content to CRM-related aspects was estimated to be approximately 1 : 1. As suggested by other authors, only short video sequences oriented to the learning objective were selected for the debriefing [9]. Each scenario included the active participation of 4–6 doctors and nurses as team members. The participants took on roles that corresponded to their position and their level of clinical training. The course participants who were not actively involved in the scenario observed the scenario from an adjoining room via video transmission. All participants were actively involved in at least two scenarios.

The simulation training was implemented using full-scale patient simulators: a SIMBaby (Laerdal, Stavanger, Norway) as a baby simulator and a Pediatric HAL Five Year (Gaumard, Florida, USA) as a small child simulator. The simulators were controlled from a control room outside of the simulated trauma room.

The course evaluation was conducted using anonymized pre- and postsurveys for evaluating the course and for a self-evaluation in regard to medical competency and CRM aspects. Participants were able to select from six response options on a scale between "I fully agree" = "1" and "I do not agree at all" = "6" for each item. The participants were given an anonymized code to allow for comparison between the pre- and postintervention surveys. The participants filled out the surveys and participated in the simulation training voluntarily. Statistical analysis was conducted using Microsoft Excel 2010. Significance was analyzed with Student's t-test; statistical significance was set at an alpha level of $p = 0.05$. All data were irreversibly made anonymous. The Ethics Committee of the Ludwig-Maximilians-University of Munich granted ethical clearance for this study, as only anonymized data were collected.

3. Results

A total of 18 pre- and 17 postsurveys were evaluated. The training included the participation of 14 doctors and 4 nurses from various fields. Of the doctors, 43 percent were residents. The allocation of the occupational groups was 43 percent pediatric surgery, 14 percent pediatrics, and 29 percent anesthesia. All participants treat severely injured children in their daily routine in a pediatric surgical emergency care outpatient center or an interdisciplinary emergency care outpatient center including trauma room. Of the participants, 71 percent reported having more than six years of work experience. 61 percent of the participants completed regular emergency training and 22 percent reported having already participated in simulation-based team training at least once in the past. Only 39 percent of the participants had completed an official pediatric emergency course of the established organizations of the European Resuscitation Council or the American Heart Association (ATLS [8], PALS [10], and EPLS [7]) over the course of the last two years prior to the trauma training.

Overall the individual course elements received a very positive evaluation (Table 2). The course was evaluated throughout as very realistic and relevant to the daily routine. Likewise, the detailed debriefings were evaluated as positive in the evaluation.

Individual aspects of this trauma training showed that even though this course was short, the individual participants felt there was a benefit for real care of children with critical trauma and found the feedback within the debriefings to be important and applicable to the clinical routine (Table 3). Contrary to the participants' expectations before the course,

Table 1: The different scenarios with their respective medical and CRM priorities.

Trauma scenario	Category	Training goal	CRM goal
Hypovolemic shock in a child with blunt abdominal trauma	C	Recognition and treatment of hypovolemic shock	Reevaluation effective communication
Maintenance two patients after MVA in the trauma room (double scenario)	A B C D	Recognition and treatment of respiratory failure, rapid sequence intubation, CPR Detecting and treating a hematothorax	Team and time management prioritization Mobilization of all available resources Get help early
Tracheal tube dislocation after repositioning the patient	A B	DOPES	Avoidance of fixing errors of the tracheal tube Mobilization of all available resources
Battered child	B D	Differential diagnosis of unconsciousness CPR algorithm	Dealing with parents Double check Use of any information
Tension pneumothorax in a major injured child with thoracic contusion	A B C	Differential diagnosis of acute circulatory insufficiency Treatment of a tension pneumothorax CPR	Prioritization team leadership anticipation
Traumatic brain injury (TBI) with secondary deterioration and seizure following sledge accident	D	Treatment of TBI and seizure neuroprotection	Prioritization (diagnostic procedures versus surgical care)

A = airway, B = breathing, C = circulation, D = disability; CRM = crisis resource management; CPR: cardiopulmonary resuscitation. DOPES: D = displacement (tube), o = Obstruction (tube), P = pneumothorax, E = equipment failure, S = stomach pressure; MVA = motor vehicle accident.

Table 2: Evaluation of the individual course elements (1 = very good, 6 = unsatisfactory, and n = number of participants).

Parameter	1	2	3	4	5	6
Overall impression	14	3	—	—	—	—
Lessons (CRM + acute trauma care, emergencies)	2	2	9	4	—	—
Realism of scenarios	9	6	1	1	—	—
Relevance of the scenarios for the practice	12	3	2	—	—	—
Debriefings	11	4	—	1	—	

Table 3: Individual marks of the course elements (n = number of participants).

Parameter	I totally agree	I agree	I tend to agree	I tend to disagree	I do not agree	I do not agree at all
In this course I got benefit for my clinical practice?	13	4	—	—	—	—
The feedback from the instructors is useful for my clinical practice?	10	7	—	—	—	—
I felt uncomfortable with video recordings during the scenarios.	—	1	—	—	7	9
I feel "paraded" during scenarios.	—	—	—	2	2	14

the video recordings taken during the scenarios for the debriefing were seen as slightly uncomfortable. Likewise, the participants did not feel like they were being put on display in the debriefings (Table 2).

The participants reported of a feeling of individual improvement in almost all categories of the medical problems they worked through (Figure 1). Special medical aspects in this regard were pediatric airway management (pretrauma course: median 3, range 1–6; posttrauma course: median 2, range 1–4; not significant (ns)), circulatory problems (pretrauma course: median 3, range 1–6; posttrauma course: median 2, range 1–4; ns), polytrauma management (pretrauma course: median 3, range 1–6; posttrauma course: median 2, range 1–4; ns), management of severe head-brain

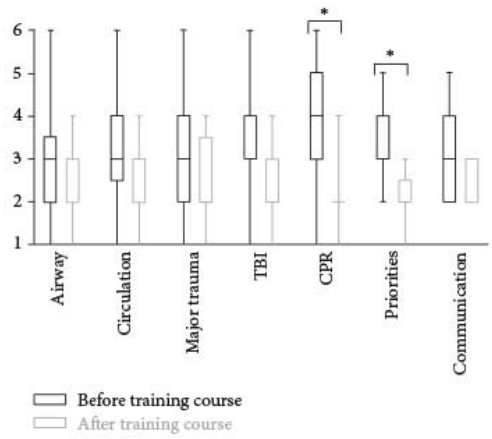

FIGURE 1: Assessment of various elements of the course pre- and posttrauma training (1 = very good, 6 = unsatisfactory, median, 25th and 75th percentiles, and span). $^{*}p < 0.001$.

trauma (pretrauma course: median 3, range 1–6; posttrauma course: median 3, range 2–4; ns), and cardiopulmonary resuscitation (pretrauma course: median 4, range 1–6; posttrauma course: median 2, range 1–4; $p < 0.001$). An improvement was likewise achieved in nontechnical skills using the example of setting priorities (pre: median 3, range 2–5; post: median 2, range 1–3; $p < 0.001$) and reliable and effective communication (pre: median 3, range 2–5; post: median 2, range 2-3; ns) (Figure 1).

4. Discussion

The pilot project described here was the first to introduce a simulator-based course concept focused on pediatric surgical trauma care in the German-speaking countries. For this project, the course concept of the PAEDSIM Working Group that was already tested in many trainings in pediatric emergencies involving over 1.000 participants was adapted to the special needs of a pediatric trauma emergency room [11]. In regard to the interdisciplinary character of trauma care, it seems to be necessary to integrate nonmedical aspects also, such as teamwork and communication, into established training concepts [12].

This becomes even more relevant in the time-critical emergency care of a pediatric trauma. In addition to a clear organizational structure and assignment of tasks, closed loop communication and clear team leadership are required in other course concepts [13–15]. Such was also demonstrated impressively in the scenarios practiced in this pilot project. The participants recognized for themselves the need for a clear team structure, especially in complex situations, for example, the maintenance of two patients after MVA in the trauma room (double scenario). This self-recognition is the basis for deep, experienced-based learning (deliberate practice) [16,17]. In this respect, we believe the opportunity of having a video debriefing is an essential basis. This view coincides with the experience of other authors [18]. Participants reported that they did not feel uncomfortable with this video recording and did not feel "paraded" during scenarios. This evaluation is important to maximize the impact of training sessions and avoiding retention, in particular for simulation-based training in Germany.

In our opinion, a simulator-based course concept with a focus on CRM cannot replace the known guideline courses of medical societies (e.g., ATLS, EPLS). It is, however, a very helpful additional course focused on the important nontechnical skills during time-critical care in a large team. The "common language" of the current algorithm-oriented course formats must continue to be a basis of interdisciplinary trauma care in pediatric patients. Only those who know what is meant by the ABCDE care algorithm can function as good team members and think with foresight. To act in this way, all trainees as stakeholders in their field work as multiplicators and are responsible for the training's acceptance within their teams.

The participants' positive evaluation of the course format in regard to the relevance to daily practice and the reality of the practiced scenarios show that the instructors have selected the right scenarios. The relevance to the daily work of each participant is an important criterion of a simulation scenario developed by the PAEDSIM Working Group. According to the opinion of the authors, standard treatment of a life-threatening injury in a child is already so demanding for a multiheaded team that a conscious decision was made to exclude other devised snares, such as a power outage and other technical problems, or the presentation of rare diagnoses [12, 19].

The positive evaluation of the debriefings supports the course format with a temporary focus on the debriefing. An appropriate amount of time is needed to work through a complex incident of this type, involving the provision of care for severely injured children. Therefore, the course planners calculated 45 minutes for each debriefing. The importance of structured debriefing for the aforementioned "deep learning" of the participants is also emphasized by other authors [20, 21]. The debriefing structure proposed by Cheng et al. was effective in the course presented here as well [22]. This debriefing method, which avoids any assignment of blame and premature judgment, is a focus of the instructor training of the PAEDSIM Working Group and contributes to the good evaluation of the debriefings by the participants (Table 3).

The participants' rather average evaluation of the theoretical part calls for a revision of this section of the course. We speculate that the presentations on trauma care in pediatric patients were not adequately adjusted to the level of the participants. Due to the pilot character of the course, the majority of participants already had many years of experience in pediatric trauma care. Here a more accurate evaluation of the participants' knowledge would have been necessary at the time of course planning. Such could eventually be evaluated using an online survey distributed prior to the course. An alternative would be to reduce the amount of time for this part of the course as a way to offer more skill stations for smaller groups. Leaning on the model of the ATLS [8]

courses, thematic preparation for the course would be done in private study with the help of a special manual. If participants were less experienced, an alternative would be to extend the duration of the course to two days, allowing sufficient time for interactive theoretical processing of the course content. In addition to resuscitation, pediatric trauma has been identified as an uncommon event that requires practice in managing. Furthermore to the ATLS trauma courses only a small component is devoted to pediatrics and in the EPLS courses specific performance about pediatric trauma has a low representation [23].

5. Summary

The objective of the present pilot project was to apply the concept of the PAEDSIM Working Group to the interdisciplinary management of pediatric trauma. We were able to show that a high-quality, simulation-based course concept can be implemented even within a narrow time frame of 1.5 days. The number of course participants is not sufficient, however, to demonstrate a subjective improvement in medical techniques and nontechnical skills based on the participants' self-evaluation. The selection of these subjective parameters as a measure of the effect of training is being viewed with increasing criticism. To evaluate the effect of simulation-based training, the personnel and organizational structure would have to remain as constant as possible and clinical quality parameters, such as the change in inner clinical care time, safety in diagnostic activities, and the quality of pediatric surgical therapy of a severely injured child, would have to be analyzed in the trauma room.

The present project is intended to serve as an impetus for further expansion of the modern and innovative educational concept of simulation-based training in pediatric surgery. This course concept is scheduled to be continued as in situ training within hospitals in the real clinical setting of interdisciplinary pediatric surgery trauma room care. This study demonstrates that simulation-based training even in pediatric trauma scenarios is feasible in an interdisciplinary setting in Germany.

Disclosure

An earlier version of this work was presented as an abstract at the 4th International Pediatric Simulation Symposia and Workshop (IPSSW 2011).

Competing Interests

The authors declare that there is no conflict of interests regarding the publication of this paper.

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REGULAR ARTICLE

Parents reported reduced symptoms and improved satisfaction after fundoplication and their perceptions were an important outcome measure

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Antireflux surgery, Fundoplication, Gastro-oesophageal reflux disease comorbidities, Parental perceptions

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ABSTRACT

Aim: Fundoplication is required for children with chronic recurrent gastro-oesophageal reflux disease (GERD). The aim of this study was to report parental perceptions of symptoms and overall satisfaction with the long-term course following fundoplication with special reference to patients with GERD risk factors.

Methods: We studied 34 patients, with a median age of 6.5 ± 4.9 years, who received fundoplication between 2001 and 2005. Clinical information and surgical complications were recorded. Parents were interviewed to evaluate post-operative symptoms, mode of nutrition and satisfaction.

Results: The median follow-up time was 7.3 years. Comorbidities were neurological impairment in 15 patients, other gastrointestinal disorders in seven patients and isolated GERD in 12 patients. The parents reported that fundoplication effectively treated initial reflux symptoms in 60% and improved symptoms in 37%. Vomiting and reflux-associated pain were treated most effectively. Pulmonary symptoms often remained unchanged in neurologically impaired children. Redo fundoplication was necessary in seven patients. Only two parents regretted consenting to surgery.

Conclusion: A high percentage of parents reported improved gastrointestinal reflux-related symptoms and a high level of satisfaction following fundoplication. Parental perceptions of GERD symptoms should be an important outcome measure when assessing the efficacy of antireflux surgery in children in routine clinical follow-up.

INTRODUCTION

Gastro-oesophageal reflux disease (GERD) is common in children, with an incidence of up to 8.3% in infants and 0.4% in children over one year of age (1). Children with congenital diseases such as oesophageal atresia, diaphragmatic hernia and severe pulmonary disorders, or those with an underlying neurological impairment, have an increased risk of GERD (2). The treatment of GERD symptoms and/or complications is primarily conservative and described in clinical guidelines (2,3). In cases where an optimised medical therapy fails or long-term medication is required for chronic recurrent GERD, fundoplication is an essential treatment option (3). The antireflux operation generally eliminates all reflux, including physiologic components, but it does not improve oesophageal clearance and therefore has no impact on motility disorders of the gastrointestinal tract (4). The downsides of surgery are high rates of complications and reflux recurrence, especially in children with GERD risk factors (5). The literature offers data regarding the long-term course after fundoplication (5,6). However, few paediatric studies have focused on parental assessments of outcome and satisfaction after antireflux surgery (7). The aim of this study was to report long-term parental perceptions of gastrointestinal and pulmonary symptoms following fundoplication, with special regard to patients in different risk groups, such as those with neurological impairment and other gastrointestinal disorders.

Abbreviations
GERD, Gastro-oesophageal reflux disease; GER, Gastro-oesophageal reflux.

Key notes

- This study reviewed parental perceptions of symptoms and overall satisfaction following fundoplication in children with risk factors for gastro-oesophageal reflux disease (GERD).
- The parent reported that fundoplication effectively treated initial reflux symptoms in 60% and that vomiting and reflux-associated pain were treated most effectively.
- Parental perceptions of GERD symptoms should be an important outcome measure when assessing the efficacy of paediatric fundoplication in routine clinical follow-up.

PATIENTS AND METHODS

After obtaining approval from the Ludwig Maximilians University's ethics committee, data from 36 paediatric patients who had undergone fundoplication due to GERD between January 2001 and February 2005 were reviewed. Two patients had died due to their underlying disease, with severe neurological impairment due to a syndromal disorder. In each case, the clinical diagnosis of GERD was confirmed by endoscopy, with biopsy, radiographic imaging of the upper gastrointestinal passage and oesophageal pH monitoring. All patients had taken antacid medication for more than 12 months. Fundoplication was increasingly performed laparoscopically, but an open approach was adopted to treat cases where adhesions were expected due to prior surgery. Fundoplication was performed using either a complete wrap or hemifundoplication as described by Thal (8,9).

The study design was a retrospective cohort study with a prospective survey of the patients' parents. Pre-operative and post-operative data were registered retrospectively from medical records and included patient morbidity, GERD symptoms, medical treatment, diagnostics, operative details, post-operative and long-term complications, including recurring reflux, revision fundoplication and continuing reliance on antacid medications. For follow-up results, parents were contacted by telephone and a semi-structured interview was performed. Questions addressed pre-operative and current nutrition, GERD symptoms leading to the decision to perform fundoplication and patient outcomes. The parents were also asked whether new problems or complications had arisen. GERD symptoms were generalised, as shown in Table 1. A post-operative symptom score was derived from a four-point-scale, where one was asymptomatic, two was better, three was no change, and four was worse. Finally, the parents were asked how they felt about their decision to agree to fundoplication for their child. Descriptive statistics with frequencies, medians and standard deviations were used to summarise the characteristics of the study sample. Data are depicted as medians or percentages of the totals unless otherwise indicated.

Table 1 GERD symptoms of the children which were required during the survey of parents

Pulmonary symptoms	• Recurrent pulmonary infections • Asthma • Dyspnoea • Chronic cough	Parents were asked to rate the symptoms on a 4-point scale: 1 = asymptomatic 2 = better 3 = no change 4 = worse
Pain due to GERD	• Dysphagia • Retrosternal pain • Heartburn	
Other GERD symptoms	• Recurrent emesis • Vomiting • Gagging • Signs of growth retardation (slowing or arrest of growth and weight gain below the third percentile)	

RESULTS

Complete information was available from 34 children who underwent fundoplication between January 2001 and February 2005. The median age at the time of the initial operation was 6.5 ± 4.9 years, with a male/female ratio of 1.2:1. The mean duration of follow-up was 7.3 ± 1.7 years. The indications for fundoplication were refractory oesophagitis in 15 patients, associated with stricture in five patients and epithelial dysplasia in seven patients, as well as persistent reflux with additional comorbidities such as severe pulmonary symptoms, hiatal hernia and failure to thrive in 21 patients. About 75% of the patients with isolated GERD had therapy-refractory oesophagitis.

The cases were divided into three groups: neurologically impaired, additional gastrointestinal disorders and children with isolated GERD. In the group of neurologically impaired children, two patients suffered from idiopathic mental retardation, one patient had chromosomal abnormalities, six patients had intracranial haemorrhage due to premature birth, four patients had central nervous system malformations, one patient had congenital cytomegalovirus infection, and one patient had perinatal asphyxia. Four children had moderate neurological deficit, and 11 children had severe neurological deficit (10). Of the seven children with other gastrointestinal disorders, the coexisting conditions included three patients with oesophageal atresia, one patient with duodenal atresia, two patients with diaphragmatic hernia and one patient with necrotising enterocolitis. The 12 children with isolated GERD had no other comorbidities. Predominant pre-operative GERD symptoms leading to the decision to perform fundoplication reported by the parents are listed in Table 2. In our 34 patients, the parents reported a total of 62 relevant symptoms, such as gastrointestinal symptoms in 42 patients, pulmonary symptoms in 20 patients and an average of 1.8 symptoms per patient.

In our study group, 41% of our patients had both pulmonary and gastrointestinal symptoms that indicated fundoplication. This was more frequent in children with neurological impairment (60%) and children with other gastrointestinal disorders (57%). Of the children with isolated reflux, only 8% had pulmonary and gastrointestinal symptoms. Therapy-refractory oesophagitis was the most frequent occurrence, in 75% of children with isolated GERD, and epithelial dysplasia/metaplasia occurred in 50%. Fundoplication was performed laparoscopically in about half of the patients. In three cases, laparoscopy had to be converted to an open surgery due to severe intra-abdominal adhesions in two patients and bleeding from the spleen in one patient. More than half of the patients in the group of neurologically impaired children and in children

Table 2 Pre-operative GERD symptoms leading to the decision to perform fundoplication as reported by the parents

	Number of symptoms (patients %)			
GERD symptoms	Total	NI*	GD†	IG‡
Vomiting	23 (68)	10 (67)	6 (86)	7 (58)
Reflux-associated pain	11 (33)	4 (3)	3 (43)	4 (33)
Nutritional problems	8 (24)	2 (13)	1 (14)	5 (42)
Pulmonary symptoms	20 (59)	13 (87)	6 (86)	1 (8)

*GERD + neurological impairment.
†GERD + other gastrointestinal disorders.
‡Isolated GERD.

Table 3 Long-term complications after fundoplication in children with GERD

	Number of patients (%)			
Long-term complication	Total	NI*	GD†	IG‡
Recurrence of reflux	9 (29)	5 (42)	2 (33)	2 (18)
Redo fundoplication	7 (21)	4 (27)	1 (14)	2 (17)
Loose fundoplication	2 (6)	–	1 (14)	1 (8)
Continuous antacid medications	10 (29)	6 (40)	1 (14)	3 (25)
Oesophagitis	11 (32)	3 (20)	2 (29)	5 (42)

*GERD + neurological impairment.
†GERD + other gastrointestinal disorders.
‡Isolated GERD.

with isolated GERD had laparoscopic fundoplication. Children with additional gastrointestinal disorders underwent open fundoplication in 86% of cases. The primary operative procedure was an anterior partial fundoplication as described by Thal in 22 patients (9) with another 12 patients undergoing Nissen fundoplication (8).

About half of the patients were fed orally before fundoplication was carried out. All children with additional gastrointestinal disorders and isolated GERD could be fed orally on a long-term basis after surgery. A total of 11 patients with neurological impairment were pre-operatively fed via a feeding tube and remained dependent on a feeding tube in the long term.

GERD recurrence was detected in nine patients during follow-up. In two patients, the fundoplication had been reversed because of severe dysphagia. A refundoplication was carried out in seven of these nine patients, because of a functional stenosis in five patients and dislocation of the wrap in two patients. Overall, 10 patients still received continuous antacid medication in the long term. The distribution of long-term complications among the groups is shown in Table 3.

Interviews with the parents revealed that in the long term, 60% of the initial reflux symptoms had disappeared, 37% had improved, 3% stayed the same, and none were exacerbated. Vomiting was most effectively addressed by fundoplication in 82% of cases and reflux-associated pain in 78% of the overall patient group. In patients with isolated reflux, vomiting was treated effectively in all of the patients and reflux-associated pain was treated effectively in 75%. Table 4 describes the effect of fundoplication on pulmonary and gastrointestinal symptoms as reported by the parents. According to the parents' perceptions, there was no significant difference between the post-operative symptom score in the group of patients with partial fundoplication according to Thal (9) compared to full-wrap fundoplication according to Nissen (8). However, the rate of continued antacid medication and refractory oesophagitis was higher in the group of partial fundoplication. A total of 10 patients experienced new problems or complications in the course of follow-up, half of them in the group of children with neurological impairment. The individual symptoms were bolus events in two patients,

Table 4 Effect of fundoplication on pulmonary and gastrointestinal symptoms as reported by the parents

	Number of patient (%)			
	Total	NI*	GD†	IG‡
Parents reporting asymptomatic				
Gastrointestinal symptoms	32 (76)	11 (37)	8 (53)	13 (72)
Pulmonary symptoms	6 (30)	3 (23)	3 (50)	0
Post-operative symptom score§	Median			
Gastrointestinal symptoms	1.2	1.3	1.2	1.3
Pulmonary symptoms	1.8	2.0	1.6	2.0

*GERD + neurological impairment.
†GERD + other gastrointestinal disorders.
‡Isolated GERD.
§Post-operative symptom score derived from a 4-point scale (1 = asymptomatic, 2 = better, 3 = no change and 4 = worse).

subileus symptoms in three patients, dumping in one patient, tracheostoma in one patient and swallowing problems in three patients. Only two of the 15 patients with neurologically impairment, three of the seven patients with additional gastrointestinal disorders and four of the 12 patients with isolated reflux were completely symptom free in the long term after fundoplication. This was equivalent to 26% of the total cohort. During the interviews, 32 of the 34 parents commented that they would consent to surgery again because of the improvement in reflux-associated symptoms and better quality of life. Only two parents regretted consenting to surgery, because their child was still an infant, too small at the time of the surgery, and they perceived it to be too much physical stress at that time.

DISCUSSION

The aim of this study was to evaluate parental perceptions of the long-term outcomes of gastrointestinal and pulmonary symptoms that had led to fundoplication in a

paediatric population, with special reference to GERD risk factors. The majority of parents reported that fundoplication improved the initial symptoms across all study groups, such as vomiting and reflux-associated pain, and expressed a high level of satisfaction. However, 21% of the patients needed another operation and this is a possible discrepancy with the parental perceptions.

Our study found a higher rate of pulmonary symptoms in patients with associated risk factors for GERD, such as neurological impairment and additional gastrointestinal disorders, compared to children with isolated GERD. All but one patient suffering from GERD and neurological deficits reported pulmonary symptoms to an extent that it led to the decision to perform surgery in the first place. Of those patients, 67% also reported gastrointestinal syndromes. This was a deviation from other published studies, where pulmonary symptoms were reported at rates of between 30% and 50% (5,11) and one study even registered a predominance of gastrointestinal symptoms of 90% (12). The cause of pulmonary infections in patients with severe neurological impairment is generally aspiration of gastric content due to gastro-oesophageal reflux (GER) or direct aspiration of food and saliva (13). The literature reports rates of up to 70% for GER and 38% for direct aspiration in severely neurologically impaired patients (14,15). We were unable to differentiate direct aspiration from GER in the patient group with neurological impairment, but only 23% of the patients in this group were free of pulmonary symptoms after fundoplication in the long term. It was very noticeable that there were a significantly higher percentage of persistent pulmonary symptoms in our study. This was in accordance with other studies, which also reported a predominance of pulmonary symptoms in the long-term course of children with neurological deficiencies after both open and laparoscopic fundoplication (16–18). Therefore, successful treatment of respiratory symptoms after fundoplication seemed to be only a short-term success in the first post-operative year that mainly affected children younger than four years (19). A number of reasons could describe the possible cause of persisting respiratory symptoms after fundoplication in children with neurological impairment, including discoordinated swallowing, gastro-oesophageal dysmotility, spasticity, aerophagy, chronic constipation, scoliosis or a predominantly supine position (20).

In children with additional gastrointestinal disorders, a combination of pulmonary and gastrointestinal symptoms was the main reason for fundoplication, with a larger number of gastrointestinal symptoms. However, pulmonary symptoms persisted in half of these patients. There was no comparative data for this in the literature, as most studies only assessed gastrointestinal symptoms after fundoplication in this patient group.

In the literature, the most important outcome parameters after fundoplication were recurrent or persistent reflux symptoms, or, in many studies, the number of repeated fundoplications. In a prospective follow-up study on the efficacy of laparoscopic Thal fundoplication, with a follow-up duration of 10 years, Mauritz et al. (21) found that approximately 40% of patients had recurrent or persistent reflux symptoms. In children with neurological impairment, the literature reports higher rates, as high as 71%, in those who underwent open surgery (17) and up to 59% in those who received laparoscopic fundoplication (5,12). Our data on patients with neurological impairment confirm these results, with recurrent reflux in 42% of these patients, but persisting gastrointestinal symptoms in only 21%. Vandenplas et al. (3) even concluded that antireflux surgery does not provide an additional benefit for patients with neurological impairment whose symptoms can be controlled well with a drug-based therapy, because of the resulting morbidity and high failure rates of the surgery. The high rate of complications in children with neurological impairment after fundoplication cannot be explained by the surgical technique (12,22). Controversial discussions suggest that gastric emptying disorders are causes of high complication rates. Gastric emptying is not negatively affected by a semi-partial fundoplication in children with neurological deficiencies (23). It remains unclear to what extent a Nissen fundoplication delays (24), accelerates or does not affect gastric emptying (25). Extreme rumination, retching and gagging can increase the complication rate due to increased intra-abdominal pressure (12) and may be responsible for a higher rate of repeat fundoplication in children with neurological deficiencies (26,27). In our study, repeat fundoplication was necessary in 21% of patients. Previous publications report between 1.7% and 18% of children required reoperation after failed fundoplication (26).

Children with isolated GERD showed the lowest rate of radiologically detectable recurring GER among our patient cohort, with only 18%. Antireflux surgery successfully treated vomiting in all patients with isolated reflux and most of the other gastrointestinal symptoms. However, persistent or recurring oesophagitis after fundoplication was the highest at 42%. Therapy-refractory oesophagitis already existed in 75% of the patients in this group before surgery.

The majority of parents in our study reported that fundoplication improved the initial symptoms across all study groups, such as vomiting and reflux-associated pain, and they also reported a high level of satisfaction. Parents also reported better well-being of neurologically impaired children after fundoplication. Thus, there is a considerable discrepancy between the parents' perceptions and our evaluated post-operative data, as described above. O'Loughlin et al. (27) surveyed 89 caregivers following antireflux surgery in neurologically impaired children. Interestingly, caregivers reported significant improvement in feeding indices and perceptions of child's comfort and child's quality of life (27). Kristensen et al. (7) also reported good parental satisfaction after fundoplication. Improvements from severe vomiting, better quality of sleep and a reduced number of episodes of pneumonia are plausible explanations for the positive outcome (7). Complications, recurrent GER and high repeat surgery rates, especially in children with GERD risk factors, are reported (12,17,21).

Surprisingly, none of the parents said their child's condition got worse after fundoplication (7). The data are in keeping with the results of our study as well as two previous studies examining caregivers' perceptions after fundoplication (27,28).

In terms of expectations of post-operative results, healthcare professionals place more emphasis on physical and medical aspects of well-being in contrast to parents who are more concerned about emotional well-being and socialisation (27). Healthcare professionals can quantify the post-operative result based on a clinical and diagnostic assessment during a short outpatient consultation. A complete evaluation of these results will only be useful if they include the parents' perceptions of their child's daily life. The attitudes and perceptions of parents are an important consideration for clinicians when developing management strategies for children and the role of the parents should not be underestimated. Even the parents of children who needed repeat surgery, reported that their child's symptoms improved and their child developed well. Therefore, indications for antireflux surgery as well as repeat surgery should be considered in view of parental perceptions of GERD symptoms during the long-term follow-up.

CONCLUSION

The majority of parents reported that fundoplication improved the symptoms for which surgery was originally undertaken. The symptoms of vomiting and reflux-associated pain were most successfully treated by fundoplication. In contrast, pulmonary symptoms largely persisted in children with neurological impairment. The repeat surgery rate of 21% in our study is not satisfactory. Considering the results of our study, parental perceptions of GERD symptoms should be an important outcome measure when assessing the efficacy of antireflux surgery in children.

CONFLICT OF INTEREST

None to declare.

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Re-operations for Hirschsprung's Disease: Long-term Complications

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Abstract

Introduction: In some patients with Hirschsprung's disease (HD), the initial surgical procedure fails, and the patients suffer from repeated or persistent symptoms. These patients complain of severe inflammation, intestinal obstruction, fecal or urinary incontinence, abdominal pain or dystrophy. However, little data has been published on the long-term follow-up results after re-operations for HD.

Materials and Methods: We followed 8 cases between 2004 and 2006, of complicated HD requiring repeated surgery and recorded prior procedures, histological results, indications for re-operation, postoperative follow-up as well as long-term clinical outcomes including stool patterns, nutrition and micturition.

Results: The follow-up period ranged from 3.0 to 5.5 years (mean: 4.4 years). Indications for repeat procedures were as follows: blind rectal pouch after a Duhamel operation (n=2), persistent aganglionosis (n=4), long-segment stenosis (n=1) after a Rehbein operation, and anal stenosis following TERPT (transanal endorectal pull-through) (n=1). In one patient who had a Duhamel-Martin operation, extirpation of the rectum and a definitive terminal ileostomy was necessary. A Duhamel procedure was performed in five patients with a primary Rehbein and 1 patient with a primary Duhamel operation. Complete stool continence was achieved in 4 patients. Partial fecal incontinence persisted in one patient with associated trisomy 21. 1 patient with total colonic aganglionosis and 1 patient with a pelvic fistula and a previous subtotal colectomy reported soiling 1–2 times per week after a repeat operation. 4 patients in our series experienced postoperative complications following repeated surgery [perianal ulceration (n=2), repeated botulinum toxin injection for sphincter achalasia (n=1) and functionally impaired colonic transit without stenosis (n=1)]. Micturition was normal in 7 patients, 1 patient with associated trisomy 21 was partially continent, and 1 patient reported infrequent urge incontinence.

Conclusions: All patients improved after further surgical intervention. However, resolution of their symptoms was delayed and partial stool incontinence or soiling persisted in 3 patients. Most complications leading to repeat procedures are preventable, especially residual aganglionosis. Therefore, great efforts should be made to minimize complications when planning and performing the primary surgery.

Introduction

In some patients with Hirschsprung's disease (HD), the initial surgical procedure with resection of the aganglionic bowel fails and they suffer from repeated or persistent symptoms [1,2]. These findings are not associated with any specific surgical procedure [3,14]. The complications include soiling, incontinence, constipation, diarrhea, abdominal pain and failure to thrive. The etiology of these problems may include severe enterocolitis, mechanical or functional obstruction, fistulas, residual aganglionosis, a hypertonic internal sphincter and severe inflammation caused by a blind rectal pouch after a Duhamel procedure. The management of these symptoms includes nonoperative treatment as well as surgical treatment. A good diagnostic work-up is essential for determining the correct therapeutic plan. There is little data published on the essentials of a diagnostic approach and the decision-making process. Apart from indications and the timing of repeated surgery for HD, long-term outcomes reporting complications and gastrointestinal function are not available.

Table 1 Data on initial case history of HD patients.

#	Sex	Aganglionic section	Initial clinical presentation	Initial procedures	Postoperative problems/further operations
1	m	recto-sigmoid	HAEC	Rehbein	required repeat sphincter dilatations
2	m	recto-sigmoid	intestinal obstruction	Rehbein	intestinal obstruction
3	f	total colonic aganglio-nosis	intestinal obstruction	Rehbein+colectomy	severe defecation problems with repeat ileostomy
4	m	desc. colon	intestinal obstruction	Rehbein	anastomotic leak, colostomy prolapse, Hartmann's procedure
5	m	recto-sigmoid	intestinal obstruction	Rehbein	Adhesion-related bowel obstruction with fistula, segmental colectomy
6	f	total colonic aganglio-nosis	intestinal obstruction	Duhamel-Martin	repeat enteritis, malabsorption
7	m	desc. colon	intestinal obstruction	Duhamel	ileus, repeat colostomy, anastomotic stenosis, abdominal wall abscess, entero-cutaneous fistula, re-re-Duhamel and Soave
8	m	recto-sigmoid	constipation	TERPT	wound infection

HAEC: Hirschsprung's disease-associated enterocolitis; desc: descending; m: male; f: female; TERPT: transanal endorectal pull-through

The aim of this study was to critically analyze patients with HD who required repeat surgery with a focus on the diagnostic approach, the reasons for failed primary surgery, and postoperative long-term gastrointestinal complications. With this report, we hope to contribute to the discussion regarding the limitations of re-operations for HD.

Materials and Methods

Between July 2004 and September 2006, 8 patients (6 boys and 2 girls) with HD underwent repeat surgery at our institution. Secondary diagnoses in our group of patients included trisomy 21 (#1), posthemorrhagic hydrocephalus and a congenital heart defect (#2) as well as mental retardation (#1, 2, 5). 7 of these patients (#1–7) were primarily operated on and treated at other pediatric surgery departments. Data prior to the repeat surgery were collected, including initial symptoms after birth, details about the original extent of the aganglionic section, the management and initial operative procedure, postoperative complications and further surgical procedures. The persistent leading symptoms, constipation and soiling patterns were recorded, and further diagnostic procedures, including radiological studies and histochemical examinations, were performed at our institution and prospectively recorded. After analyzing the data, treatment options were discussed with the patient and parents. Long-term follow-up information was obtained from outpatient visits, telephone interviews and short-term admissions for diagnostic procedures.

The diagnostic work-up included a detailed history, physical examination, contrast enema, and examination under anesthesia with a rectal biopsy for histological evaluation. In some cases, a 3-dimensional vector manometry study (3D-VM), cystomanometry or magnetic resonance imaging (MRI) was performed.

Results

The age of the patients at the repeat procedure ranged from 5 months to 14.6 years, (average: 7.6 years). Data on the initial case history, postoperative problems and further operations of all patients are shown in **Table 1**. These data include the aganglionic segment, as determined by the initial surgery, initial clinical presentation and primary procedure. All patients had an enterostomy, performed as the first surgical intervention. In 7 patients, enterostomy was performed during the first postnatal weeks (#1–2, 4–8), and in 1 patient, it was performed at the age of 5 months (#3). 1 patient (#8) still had the primary enterostomy, 2 patients (#3, 4) required a re-enterostomy during prior operations and 5 patients underwent a repeat enterostomy (3 colostomies, 2 ileostomies) before definitive surgery.

The symptoms and diagnostic work-up prior to the repeat operation as well as the technique for repeat procedures are shown in **Table 2**.

In 4 patients (#1, 2, 3, 4), the reason for failure of the initial Rehbein procedure was residual aganglionosis of 6–10 cm. 1 patient (#5) developed long-segment stenosis (20 cm) of the distal colon because of a pelvic fistula that formed after a primary Rehbein procedure. A Duhamel procedure with an ascendo-anal anastomosis was performed. Before closure of the ileostomy, a stenosis of the ileocecal valve was discovered radiologically, and a stricturoplasty was performed at the time of ileostomy closure.

In 2 patients (#6, 7), the reason for the failure of the initial Duhamel-(Martin) procedure was a blind rectal pouch with an anastomotic stenosis (#6, 7) and a pelvic abscess with a fistula (#7). Patient #6 had total colonic aganglionosis, and a Duhamel-Martin procedure was initially performed. After closure of the primary ileostomy, the patient suffered from repeated intestinal obstruction with severe enteritis and required partial parenteral nutrition. The first steps were adhesiolysis and repeat ileostomy. After a 10-month recovery period, the neorectum was resected with the goal of performing a repeat pull-through. Unfortunately, due to very short mesenteric vessels, the bowel could not be mobilized enough for another pull-through, and a definitive terminal ileostomy was required. Because of an anastomotic stenosis following a Duhamel procedure, patient #7 required a repeat colostomy. Postoperatively, abdominal wall abscess formation and an entero-cutaneous fistula resulted in repeat re-operations. The diagnostic work-up revealed a pelvic abscess and fistula formation (**Fig. 1a**), beginning sacral osteomyelitis and a blind rectal pouch (**Fig. 1b**).

1 patient (#8) developed anal stenosis after TERPT (transanal endorectal pull-through) with a protective colostomy. Causative factors were a wound infection and enterocolitis.

Table 2 Diagnostic work-up, medical findings, indications for repeat procedure and description of the repeat procedure in HD patients.

	Symptoms before repeat procedure	Diagnostic techniques	Medical findings and indications for repeat procedure	Repeat procedure
1	chronic severe constipation, fecal incontinence	contrast enema rectal biopsy 3D VM	narrow rectum, megacolon **residual aganglionosis** ↑ pressure, normal symmetry	Duhamel
2	chronic severe constipation, soiling	contrast enema rectal biopsy 3D VM	narrow rectum, megacolon **residual aganglionosis** ↑ pressure, normal symmetry	Duhamel
3	ileostomy	contrast enema rectal biopsy	narrow rectum **residual aganglionosis**	Duhamel-Martin
4	colostomy	contrast enema MRI rectal biopsy 3D VM	long Hartmann (20 cm) no abscess/fistula **residual aganglionosis** ↑ pressure, normal symmetry	Duhamel ascendo-anal
5	ileostomy	CMM, VCUG contrast enema rectal biopsy 3D VM	↓ bladder capacity, no VUR **long-segment stenosis** normal findings normal findings	Duhamel ascendo-anal and stricturoplasty
6	intestinal obstruction, failure to thrive, fecal incontinence, partial parenteral nutrition	contrast enema MRI rectal biopsy	**blind rectal pouch with anastomotic stenosis** no abscess/fistula high-grade inflammation	adhesiolysis and ileostomy, resection of neorectum with terminal ileostomy
7	failure to thrive, fecal incontinence, pain	contrast enema MRI rectal biopsy	**blind rectal pouch, pelvic abscess with fistula, sacral osteomyelitis** high-grade inflammation	extirpation of pelvic abscess with resection of neorectum and ileostomy, pull-through with ileo-anal anastomosis
8	colostomy, perianal ulcerations	contrast enema	**high-grade anal stenosis**	TERPT

MRI: magnetic resonance imaging: CMM: cystomanometry; VCUG: voiding cystoureterogram; VUR: vesicoureteral reflux; 3D VM: 3-dimensional vector manometry study; TERPT: transanal endorectal pull-through

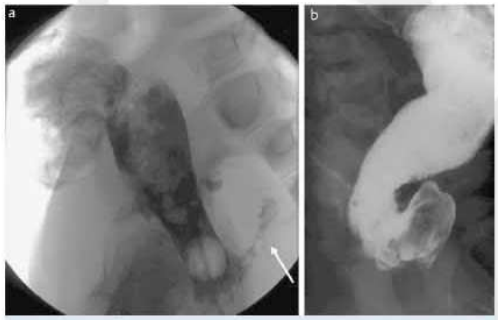

Fig. 1 Radiographic finding of a patient with HD (#7) after Duhamel procedure with a pelvic abscess, dorsal fistula (↑) **(a)** and blind loop syndrome **(b)**.

Follow-up after definitive surgery ranged from 3.0 to 5.5 years, with an average of 4.4 years (○ **Table 3**). 4 patients remained completely stool continent (#2, 4, 7, 8). However, patient #2 required laxatives and an enema once or twice a week for obstructive symptoms. Diagnostic work-up in this case revealed a functionally impaired colonic transit without stenosis. Patient #4 suffered from sphincter achalasia with constipation and fecal incontinence at follow-up. After 3 treatments with injections of botulinum toxin into the sphincter, he became continent and reported only recurrent abdominal pain about once a month. 2 patients in our series achieved partial continence (#3, 5). Only patient #1 with trisomy 21 remained stool incontinent after a repeat Duhamel operation. Medication with intermittent oral metronidazole improved stool consistency and meteorism, but the patient still refuses toilet training due to his underlying trisomy 21.

Discussion

Levitt et al. described an algorithm for the work-up and management of patients with HD who do not do well after their initial surgical procedure [4]. On initial assessment they review the history and physical examination, perform a rectal biopsy, and observe anatomical problems on a contrast enema [4]. We performed the same work-up, and in all of our patients the underlying cause of symptoms was a mechanical obstruction, due to residual aganglionosis or anatomical problems related to the initial procedure. Other authors have also found a contrast enema to be extremely useful for understanding the etiology of symptoms [5,6]. MRI was performed for a suspected abscess or fistula. For a functional diagnosis, 3D vector manometry was performed when the patient tolerated an anal examination. Computerized 3D vector manometry allows the pressure architecture of the anal canal to be studied [7]. Before repeated surgery, 3 patients (#1, 2, 4) had increased vector volumes, and one of them (#4) had to be treated after a repeat procedure due to sphincter achalasia. We did not find any sphincter insufficiency during 3D vector manometry.

Our study demonstrates that repeat surgery after a primary Rehbein procedure becomes necessary mostly as a result of residual aganglionosis, reflecting similar reports in the literature [8–10]. Constipation after a Rehbein procedure occurs in 15.4–22.8 % [11,12] of patients and depends on the length of the aganglionic segment left *in situ* as well as the additional hypoganglionic border of the resected segment [11]. In our patients with an initial

Table 3 Follow-up of HD patients, including toilet habits, nutrition, symptoms and other problems/complications after repeat procedure.

#	Repeat procedure	Fecal continence	Frequency of defecation	Stool consistency	Micturition	Nutrition	Symptoms	Problems/ complications	Follow-up (years)
1	Duhamel	not continent (soiling during the night), requires diapers	2/d	loose	partially continent	normal	recurrent meteorism due to suspected bacterial miscolonization	refuses toilet training	4.5
2	Duhamel	fully continent	3–4/d	normal under laxatives	normal	normal	obstructive symptoms, enema (1–2/week)	functional impaired colonic transit without stenosis	3.0
3	Duhamel-Martin	partial soiling (1–2/wk)	8/d	liquid	normal	diet because of food intolerance	tendency to perianal ulceration	rectal tenesmus during physical activity	4.1
4	Duhamel	fully continent	1–3/d	loose	normal	diet because of food intolerance	recurrent abdominal pain (1/month)	none	3.6
5	Duhamel and stricturoplasty	partial soiling (1–2/wk)	4–6/d	liquid	infrequent urge incontinence	normal	recurrent abdominal pain/ meteorism (1/week)	none	4.1
6	terminal ileostomy	terminal ileostomy	3/d (ileostomy bag)	liquid	normal	normal	none	iron deficiency	5.5
7	pull-through with ileoanal anastomosis	fully continent	3/d	liquid – loose	normal	normal	none	none	5.2
8	redo TERPT	fully continent	6–8/d	loose	normal	lactose intolerance	tendency to perianal ulceration	repeated diarrhea with liquid stools (1/month)	5.2

TERPT: transanal endorectal pull-through; d: day

Rehbein procedure, this study reveals that the original anorectal aganglionic segment left *in situ* was too long because the anastomosed part of the bowel was normoganglionic on histological examination. Consequently, obstructive symptoms were not of secondary origin in terms of acquired intestinal dysganglionosis or incomplete resection of the transitional zone. Other studies have proposed bowel ischemia from insufficient blood supply as well as stretching, kinking or twisting of the proximal bowel to be a further cause of secondary aganglionosis [13,14]. The risk of compromising the blood supply during a Rehbein procedure may depend on the initial extent of the necessary resection, preexisting enterocolitis and the skill of the surgeon. To avoid a repeat operation because of residual aganglionosis after a Rehbein procedure, the remaining rectum should be short enough and kinking and twisting must be prevented. Because of impaired relaxation of the aganglionic distal rectum, obstructive symptoms are common [15]. A Rehbein procedure may not be the currently preferred technique for HD. In their study Visser et al. even suggested that the Rehbein procedure is obsolete, preferring to perform a transanal endorectal pull-through with a short muscle cuff [16].

Follow-up of our patients with residual aganglionosis after an initial Rehbein procedure revealed that half of them (n=2) were completely continent; however, one suffered from mild obstructive symptoms. The patient with total colonic aganglionosis (#3) and the patient with trisomy 21 (#1) were not continent. Several authors have reported a higher incidence of soiling and constipation after a pull-through operation in children with HD and associated trisomy 21 [17,18]. Schweizer [9] reported a better clinical outcome with completely normal stool patterns in 10 of 12 patients followed up after a repeat procedure was necessary because of residual aganglionosis after a Rehbein operation.

Operatively treated postoperative stenosis requiring further surgery occurred in 3.3–13.1% of patients after a Rehbein procedure [11,12,19]. We saw 1 patient (#5) with long-segment stenosis in our repeat group who had had a previous pelvic fistula. Although this patient initially only suffered from short-segment HD, complications from the primary procedure in effect led to the necessity for a subtotal colectomy with an ileostomy before definitive correction was possible. This course may be attributed to technical errors, stenosis formation, or residual aganglionosis. On follow-up, this child was soiling intermittently and had a high frequency of defecation; however, taking the course of this patient into account, it must be considered a good overall result. Schweizer [9] described 2 cases with severe anastomotic stenosis combined with fistulas after a Rehbein operation and reported a good result with stool continence after the repeat procedure.

In the literature the indications for repeat surgery after an initial Duhamel operation are mainly due to obstructive symptoms caused by residual aganglionosis of the proximal bowel [8,20,21]. Another cause for obstruction and enteritis is a tech-

nical failure of the Duhamel operation with incomplete division of the colorectal septum. Sometimes, repeated septal divisions with a stapling device can cure these patients [22]. Pena [23] reported the necessity of a repeat pull-through in this patient group because of fecal impaction, megarectal pouch or pouchitis. Similar to this report, in our study, two patients suffered from a blind rectal pouch after a Duhamel operation, and one of them had a history of repeated operations and a pelvic abscess. On follow-up, this patient was completely continent with an increased frequency of defecation. Cases of short mesentery vessels preventing a repeat pull-through operation have been published in the literature [23]. This was the unfortunate situation for patient #6 who required a permanent ileostomy. In addition, this child had total colonic aganglionosis, and it is well known that these patients are at a significantly higher risk for postoperative complications [24].

The Duhamel procedure is commonly used for repeat operations, and authors report complete stool continence without obstructive symptoms in 43–82 % of patients [2,9,20,21,25,26]. The advantages of the Duhamel procedure for repeat operations derive from the side-to-side anastomosis, which is ideally suited for widening an anastomotic stenosis after a Rehbein operation while at the same time covering the plane of the Rehbein anastomosis, from which fistulas may originate, with healthy bowel from the re-pull-through [5,9,20]. Furthermore, clinical and anatomical studies have shown that dissection of the retrorectal and presacral compartment in the Rehbein procedure are associated with the most extensive formation of scarring compared to other techniques [9]. Endorectal pull-through (Soave technique) is also frequently used for repeat procedures [8,21] and has reported outcomes of 50 % normal stool patterns without soiling or constipation [8]. TERPT represents the latest development in repeat techniques with good functional results compared with standard pull-through procedures [27,28]. Following an initial TERPT, a repeat pull-through was necessary in 14 % of patients due to an anastomotic stenosis, a constricting muscle cuff or a twisted pull-through [29,30]. Complications after a repeat TERPT are seen more frequently than during the initial procedure; however, both anastomotic stenosis and enterocolitis responded to conservative management [27]. Long-term severe perianal ulceration (excoriation) has been a problem for 1 of our patients following repeat TERPT. Because food intolerances proved to be part of the problem, a restrictive diet resolved the symptoms. This postoperative complication has not been investigated or discussed previously in the literature.

Postoperative complications after repeat operations develop in up to 33 % of patients. These complications include wound infections, perirectal abscess formation, anastomotic stenosis, adhesions, intestinal obstruction, incisional hernia and enterocolitis [8,9,21,26]. 4 patients in our series experienced postoperative complications: perianal ulceration in 2 patients, sphincter achalasia requiring repeated botulinum toxin injection in 1 patient, and functionally impaired colonic transit without stenosis in 1 patient.

In the literature, a significant percentage of patients suffer from micturition disturbances after a primary procedure for HD [25,31]. Moore reported micturition disturbances in 9.8 %, and it was more common in patients with a Duhamel operation than in those with an endorectal pull-through [3]. Repeated operations in the pelvis are most likely to increase micturition disturbances. In our study, micturition was normal for 7 patients; 1 patient with associated trisomy 21 was partially continent, and 1 patient reported infrequent urge incontinence.

Conclusion

In conclusion, all patients improved after the repeat operation, and we achieved an outcome that is comparable to that of other series. The final results of our patients with complicated Hirschsprung's disease, which include soiling in 3 of our patients and a permanent stoma in 1 of our patients, are encouraging, but patients have obvious long-term sequelae and delayed resolution of their clinical situation. Most complications leading to repeat procedures are preventable by experienced pathologists and surgeons. A great effort should be made to minimize complications and to avoid the need for a repeat procedure.

Conflict of Interest: None

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ORIGINAL ARTICLE

Improving postoperative pain management in children by providing regular training and an updated pain therapy concept

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Abstract

Background: In recent years, children's hospitals have increasingly implemented postoperative pain management protocols to reduce postoperative pain and improve patient satisfaction. The effectiveness and long-term sustainability of such protocols have rarely been studied. Therefore, we conducted a prospective intervention study to assess the impact of regular training and improvement of clinical processes on the quality of postoperative pain management.

Methods: We conducted an initial assessment of the status quo of postoperative pain management (Audit 1) followed by repeated training and improvement of clinical processes (analgesic pocket card, parents' brochure, modification of the patient chart, bimonthly advanced trainings sessions) and a follow-up review after 3 years (Audit 2). We used a data entry form, a patient survey, and an anonymous questionnaire for the nursing staff as measurement tools.

Results: Our analysis included a total of 93 and 85 patients in the initial and final audits. The return rates of the nursing staff questionnaire were 83% (Audit 1) and 77% (Audit 2). The training and process improvements resulted in significant improvement in the administration of analgesics for pain requiring treatment, the control of pain measurement after the administration of analgesics and the use of non-pharmacological pain therapies. The patients reported faster administration of analgesics for acute pain and improved pain relief following the intervention.

Conclusions: Repeated training and improvement of clinical processes can significantly improve the long-term quality of postoperative pain management in children with a tolerable amount of effort on the part of health care professionals and institutions.

1. Introduction

Untreated postoperative pain can cause physical complications, increased incidence of post-traumatic stress and long-term behavioural changes (Kain et al., 1996; Kotiniemi et al., 1997; Sutters and Miaskowski, 1997; Taddio et al., 1997). Children's hospitals have increasingly implemented postoperative pain management protocols in recent years on the basis of existing revised treatment standards (Messerer et al., 2011; Association of Paediatric Anaesthetists of Great Britain and Ireland (APAGBI), 2012; Apfelbaum et al., 2013). Such protocols include reliable and age-related pain measurement as well as effective perioperative pain therapy (Büttner et al., 1998; Hicks et al., 2001; McGrath et al., 2008). The goals are to reduce postoperative pain and improve patient satisfaction. Although implementations of such pain management protocols

What's already known about this topic?

- Untreated postoperative pain in children can cause physical complications, increased incidence of post-traumatic stress and long-term behavioural changes.
- In recent years, children's hospitals have increasingly implemented postoperative pain management protocols to reduce postoperative pain and improve patient satisfaction.
- There are scarce data regarding the effectiveness and long-term sustainability of such protocols.

What does this study add?

- Repeated training and improvement of clinical processes can significantly improve the long-term quality of postoperative pain management in children.
- This improvement was achieved with a tolerable amount of effort on interventions and training of health care professionals.

are well documented (Ellis et al., 2007; Megens et al., 2008; Trudeau et al., 2009; Messerer et al., 2011), there are scarce data regarding their effectiveness and long-term sustainability (Balga et al., 2013). Therefore, we studied the influence of regular in-house training and improvement of clinical processes on the quality of postoperative pain management.

2. Methods

We conducted a prospective intervention study to assess the development of the quality of postoperative pain management in the paediatric surgery department of the University of Munich. An initial assessment of the status quo of postoperative pain management (Audit 1) was performed between September 2007 and March 2008. Following the first audit, three in-house training sessions were conducted for the entire medical staff, and several conceptual changes in our pain therapy management regime were implemented. A second assessment of postoperative pain management (Audit 2) was conducted from March 2011 to August 2011. Each audit included a data entry form, adopted from the implementation of the expert standard 'pain management in nursing acute pain' (German Network for Quality Development in Nursing (DNQP), 2003), a patient survey and an anonymous questionnaire for the nursing staff. Details of the audit methods are shown in Fig. 1.

All infants and children with acute pain who were admitted to the paediatric surgery unit for postoperative care were eligible for inclusion in the study. Exclusion criteria were language barriers, patients with learning difficulties, chronic pain and cancer. Each patient was included only once in the audit. Informed consent was obtained from the patients and parents before data collection.

In Audits 1 and 2, the auditor collected data from 20 charts per unit and interviewed the respective patients over a period lasting up to 6 months for a total of 100 patients per audit. A single auditor attended each unit at random 2 days per week, collecting all patient data and conducting the interviews for the patient survey. The data were collected from each of the units until the required number of patients (n = 20) from each unit was met.

The anonymized data entry form consisted of 14 questions on outcome criteria (German Network for Quality Development in Nursing (DNQP), 2003). The auditor performed a comprehensive examination of all aspects of the patient charts to locate data on the history of pain, pain assessment, pain management, pain prevention, treatment of the side effects of pain therapy and non-pharmacological pain therapies (seven questions). Pain was evaluated in children <4 years of age using the KUSS-pain score (Büttner et al., 1998). A self-assessment using the face scale of Hicks was used for children older than 4 years of age (Hicks et al., 2001). Each rating system is scaled from 1 (no pain) up to 10 (the worst possible pain). Pain was assesses at the frequency prescribed by the general guidelines of the hospital's nursing department. Pain therapy was prescribed preoperatively based on the revised standardized postoperative pain management regimen of our department as published in 2002 (Till et al., 2002). The regime included analgesics administered on a regular basis according to the extensiveness of the operation and on an as-required basis according to persistent pain as measured by a pain score. The pre-existing hospital-wide practice standard providing the appropriate frequency of pain assessment with age-appropriate pain scales, constant pain documentation and the systematic therapeutic concept in postoperative care were available for the medical staff.

One extra question on the data entry form for the nursing staff included an oral survey of the responsible nurse on the issue of the implementation of the current procedural rules for postoperative pain management. The answer on the

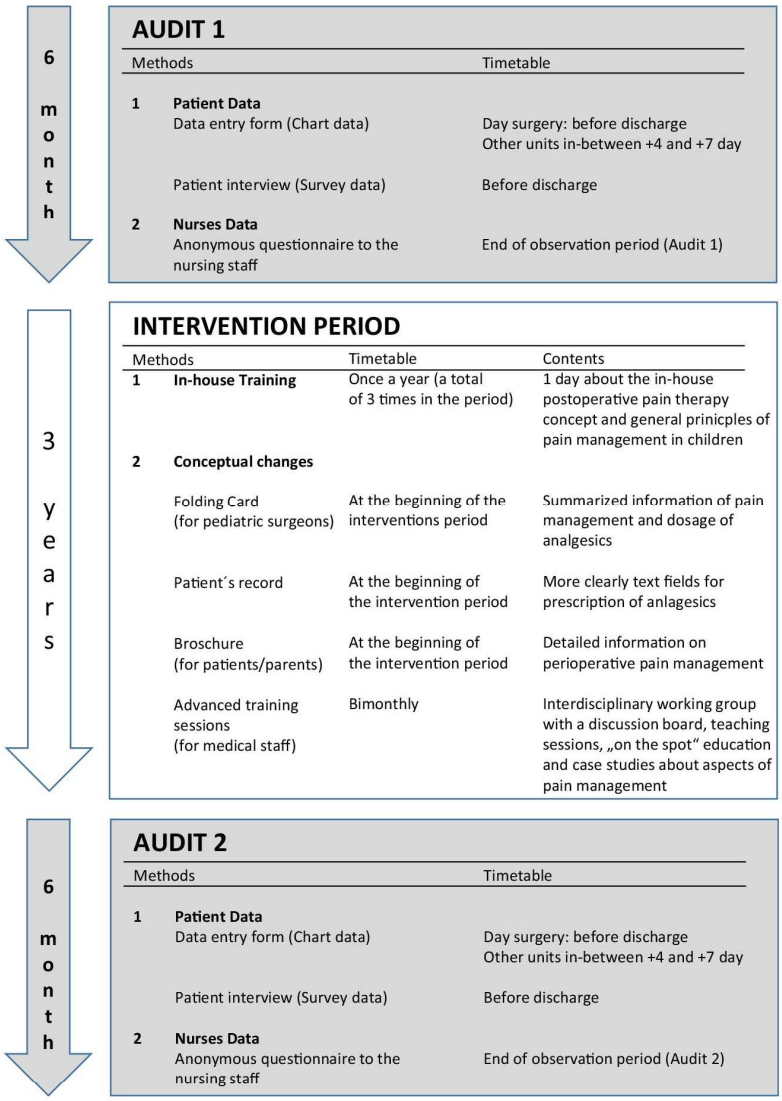

Figure 1 Diagram of the study design.

anonymized data entry from was coded to reflect whether or not all the features of the existing standardized postoperative pain management regime were fully upheld. Details are shown in Table 3 (column 'Methods').

The pseudonymized patient survey, which was distributed to all included patients or parents on surgical wards, was carried out as interview before discharge. The six questions were answered by the patients (children >10 years of age) or their parents (children <10 years of age). The possible answers were 'yes' and 'no' with the additional possibility of a comment. The percentages of 'yes' and 'no' responses relative to the total number of patients in each audit were calculated.

The anonymous questionnaire for the nursing staff was distributed to all nurses who were on duty in one of the paediatric surgery wards during the two observation periods and included 16 questions on the following topics: pain assessment, practicality of pain scores, quality of pain therapy including prescribing practices, use of non-pharmacological pain therapies, prophylaxis of procedural pain, and training and education for pain management.

The training for the nursing staff and paediatric surgeons was carried out via in-house sessions lasting

1 day and focused on the concept of pain management in the paediatric surgical clinic and on the general principles of pain management in children (basic principles and pathophysiology, pain assessment, analgesics, non-pharmacological pain therapies, adjuvant therapies, homoeopathic pain therapy, analgesia and sedation for procedural pain, and postoperative pain therapy). Following Audit 1 and in addition to the three in-house training sessions, an updated pain therapy concept was implemented with several conceptual changes of our pain therapy management regime (Table 1).

2.1 Statistical analysis

Descriptive statistics (frequency, mean) were used to summarize the characteristics of the study sample. Chi-square analysis and Student's *t*-tests were conducted to compare the results of the document analysis, patient survey, and questionnaire to the nursing staff between the first and second audits. $p < 0.05$ was considered to indicate a statistically significant difference between the answers to the questions in the first and second audits.

3. Results

The first audit was performed between September 2007 and March 2008. Audit 1 included a total of 93 patients comprising complete data sets. All members of the nursing staff during the period of Audit 1 received the anonymous questionnaire ($n = 53$). Following the first audit, beside three in-house trainings, several conceptual changes of our pain therapy management regime were done. The three in-house training sessions were conducted for the entire medical staff, with participation of a total of 65 nurses and 18 paediatric surgeons. The second audit (Audit 2) was conducted from March 2011 to August 2011 and included a total of 85 patients. All members of nursing staff ($n = 51$) received the anonymous questionnaire during the period of Audit 2. The demographics of the patients and the characteristics of the nurses are presented in Table 1. Summary of the results from the data entry form for Audits 1 and 2 is shown in Table 2. Summary of the answers to the patient survey in Audits 1 and 2 is shown in Table 3.

The response rates of nursing staff members to the anonymous questionnaire were 83% ($n = 44$) and 77% ($n = 39$) in the first and second audits, respectively. The main results of the questionnaire to the nursing staff are presented in Table 4.

Table 1 Demographic data with patients and nurses characteristics for Audit 1 and Audit 2.

Demographic data	Audit 1	Audit 2
Patients characteristics		
Age mean (SD)	5.9 (5.1)	7.7 (6.1)
Sex (Male: Female)	1.7	1.2
Type of surgery		
Orthopaedic (*n*, %)	23 (25%)	21 (25%)
Abdominal (*n*, %)	23 (25%)	26 (30%)
Genito-urinary (*n*, %)	29 (31%)	23 (27%)
Plastic surgery (*n*, %)	18 (19%)	15 (18%)
Nurses characteristics		
Age		
22–34 years (*n*, %)	20 (45%)	19 (49%)
35–47 years (*n*, %)	13 (30%)	8 (20%)
48–61 years (*n*, %)	11 (25%)	12 (31%)
Sex		
Male (*n*, %)	0 (0%)	0 (0%)
Female (*n*, %)	44 (100%)	39 (100%)
Paediatric nurses (*n*, %)	44 (100%)	39 (100%)

4. Discussion

The primary purpose of continuing education in medicine is to maintain and improve clinical performance (Cantillon and Jones, 1999). To change clinicians' behaviours and achieve overall improvements, a combination of continuing education, organizational factors and contact with other health care professionals is necessary (Ashford 1999). The long-term implementation of educational programmes to improve clinical performance in postoperative pain therapy in children is difficult. In our study, improvement was achieved in most aspects of postoperative pain management after multifaceted interventions and repeated education of the medical staff over a long period.

Sixty-four per cent of the parents and patients surveyed felt well informed about the expected pain and pain-related treatment in Audit 2, whereas before the intervention only 8% (Audit 1) felt well informed. That improvement was achieved by providing a detailed, generally understandable patient brochure about postoperative pain management and by increasing the use of pain surveys at the beginning of hospitalization by the nursing staff along with face-to-face education about postoperative pain management. Other studies have indicated that educational booklets, face-to-face teaching and video distribution are helpful for increasing parents' knowledge of pain management and improving attitudes towards pain medication (Huth et al., 2003; He et al., 2014).

Table 2 Results from the data entry form for Audit 1 (n = 93) and Audit 2 (n = 85).

Data entry form	Method	Audit 1 (%)	Audit 2 (%)	
Survey at the beginning of hospitalization, whether the patient had pain or pain-related problems before the planned surgery	Standardized Interview with the patient/ parents	25	51	$p < 0.05$[a]
Systematic pain assessment by detected pain	Documentation of pain score (Kuss-pain score/face scale) according to the procedural rules	95	89	NS[a]
Current and systematic follow-up of the pain score	Documentation of pain score (Kuss-pain score/face scale) according to the procedural rules	88	89	NS[a]
Immediate treatment of pain in a pain score > 3/10	Administration of analgesics directly after measuring a pain score > 3/10	32	84	$p < 0.05$[a]
Review of the effect of analgesics at appropriate intervals	Documentation of a pain score (Kuss-pain score/face scale) 30 min after administration of analgesics	19	56	$p < 0.05$[a]
Offer of prophylaxis and/or treatment of pain-related side effects	Documentation of e.g. therapy of emesis, constipation, or urinary retention	23	39	$p < 0.05$[a]
Use of non-pharmacological pain therapy	Documentation of e.g. physical methods, emotional support, or cognitive-behavioural methods	16	14	NS[a]
Were you able to implement the current procedural rules of postoperative pain management?	Question to the responsible nurse	84	99	$p < 0.05$[a]

[a]chi-square analysis, NS = not significant.

Table 3 Results of the answers to the patient survey for Audit 1 (n = 93) and Audit 2 (n = 85).

Patient survey	Audit 1 (%)	Audit 2 (%)	
Have you been asked regularly about pain?	85	98	$p < 0.05$[a]
Did you immediately receive analgesics by specified pain?	60	94	$p < 0.05$[a]
Have you been pain-free after taking the analgesics or the pain was at least tolerable?	58	93	$p < 0.05$[a]
Are you been offered analgesics before painful procedures?	6	28	$p < 0.05$[a]
Are you been offered non-pharmacological pain therapies?	16	63	$p < 0.05$[a]
Have you/your family been offered information on dealing with pain?	8	64	$p < 0.05$[a]

[a]chi-square analysis, NS = not significant.

Table 4 Main results of the questionnaire to the nursing staff for Audit 1 and Audit 2.

Questionnaire to the nursing staff	Audit 1	Audit 2	
Using the pain-measurement tool	81%	75%	NS[a]
Routine of pain assessments with the pain-measurement tool	63%	68%	NS[a]
Evaluation of the pain-measurement tool (according to school grades; 1 = very good)			
KUSS	1.9	1.8	NS[b]
Faces scale	2.0	2.0	NS[b]
Satisfaction with pain therapy on the ward (according to school grades; 1=very good)	2.4	2.2	NS[a]
Early prescription of analgesics (before surgery)	86%	94%	NS[a]
Prescription of analgesics on a regular basis	88%	100%	NS[a]
Review of the effect of an administered analgesic	68%	98%	$p < 0.05$[a]
Training on pain management in the past 24 months	17%	79%	$p < 0.05$[a]

[a]chi-square analysis, [b]Student's t-test, NS = not significant.

The most effective way to treat postoperative pain is to regularly provide analgesics and to proactively prevent pain (Kokki, 2003; Messerer et al., 2010). Therefore, providing analgesics on regular basis is an important part of the quality of postoperative pain management. In our study, the percentage of nurses reporting the preoperative prescription of pain therapy was 86% and 94% in Audits 1 and 2. The percentage of nurses reporting that analgesics were prescribed preoperatively on a regular basis was 88%

and 100% in Audits 1 and 2. The changes in the responses to the nurses' survey were not significant. We hypothesize that the nursing staff overestimated the quality of pain management in the subjective survey.

Postoperative pain assessment was frequently performed in our hospital prior to the intervention and following the intervention (systematic pain assessment: 95% vs. 89%; follow-up: 88% vs. 89%). The nursing staff has been performing systematic pain assessments with an age-adapted pain score routinely since 2002. The use of the pain measurement tool was satisfactory in both audits, and was deemed favourable and valuable. Systematic pain assessment is an important step towards improving children's pain management (Dalton et al., 1999; Franck et al., 2000, 2007). Other studies have shown that nurses believed they were better able to assess pain after a comprehensive educational programme (Ellis et al., 2007). Paediatric nurses who received individualized coaching and feedback based on an audit increased their use of documented pain assessment (Johnston et al., 2007). The results of the patient survey in our study showed that with respect to pain assessment, the intervention improved pain therapy management by increasing the awareness of the nursing staff to actively ask about pain. Ninety-eight per cent of the patients or parents responded positively to being given a pain assessment questionnaire in Audit 2 compared with 85% in Audit 1. Based on a systematic review of 23 studies, Ista et al. concluded that while implementation strategies to improve nurses adherence to pain assessment recommendations vary, a multifaceted approach with educational and feedback strategies are often used and seem to be largely effective (Ista et al., 2013).

The percentage of patients, who were immediately offered analgesics for a pain score >3/10, improved significantly from 32% in Audit 1 to 84% in Audit 2. This was confirmed by the patient survey, which showed that analgesics were significantly more likely to be offered for pain after the intervention (60% vs. 84%). Accurate pain assessment is always linked to appropriate pain-control measures so that individualized titration of analgesia can be offered (Morton, 2012). In our study, the interventions greatly increased pain treatment for pain scores >3/10, indicating that the repeated training increased analgesic administration. Corwin et al. reported similar results, showing that a multidisciplinary approach with an education programme for house staff and nursing as well as handouts and brochures for patients and parents about pain management increased the use of analgesics for patients with a pain score of at least 4/10 in a paediatric emergency department (Corwin et al., 2012).

The intervention in our study increased the rate of pain assessment follow-up 30 min after the administration of analgesics from 19% to 56%. That result coincides the percentage of nurses reporting follow-up of pain measurement increasing from 68% to 98%. The lower rates of follow-up reported in the first audit could be explained by insufficient documentation of the pain score or failure to use the pain score in follow-ups. The patient survey showed that the percentage of patients who were free of pain after the application of analgesics was 58% and 93% in Audits 1 and 2. This suggests that the intervention substantially improved the success rate of the pain reassessment and therapy. In an intervention study with a pre-post design, Habich et al. also found a significant increase in pain reassessment following the implementation of Paediatric Pain Assessment and Management Guidelines (Habich et al., 2012).

The reported use of non-pharmacological pain therapies increased both in the document analysis (18–46%) and in the nurses' survey (16–63%), suggesting that the interdisciplinary training of the nursing staff with simple and practical advice on the implementation of non-pharmacological pain therapies had a positive impact. In agreement with our results, He et al. showed that educational interventions with regular dissemination of updated information had a positive effect on nurses' use of non-pharmacological methods in children's postoperative pain management (He et al., 2010). In a survey using a Likert-type questionnaire to the nursing staff, the nurses' competence and insecurity had a more substantial effect on the use of non-pharmacological methods for managing paediatric patients' surgical pain than did work-related factors or characteristics of the child and/or the child's parents. The experience and education of the nursing staff plays a central role in effective application of non-pharmacological methods (He et al., 2011).

Analgesia before painful procedures in the postoperative course was improved by the intervention (documentation analysis: 23% vs. 39%; patient survey: 6% vs. 28%) but remained altogether unsatisfactory. Following our study, a revision and improvement of the pain therapy standard for painful procedures was implemented by offering non-invasive applications of analgesics, higher variability of analgesics, and sedation according to the extent of the procedure and the patient's age. Other studies have demonstrated insufficient management of procedure-related pain in

children (Cramton and Gruchala, 2012; Morton, 2012). One possibility for the implementation of procedural sedation-analgesia was shown by Po et al., who used a procedural pain service including an organized training programme with frontal education and experience-based training (Po et al., 2012). That approach is, however, associated with high costs in terms of the requirements for highly skilled medical staff to dedicate substantial time to the training.

Our results show that regular training of the health care professionals and improvement of clinical processes led to a significant improvement in the quality of postoperative pain management. Seventy-nine per cent of the nurses who answered the questionnaire in Audit 2 reported that they participated in the training. Those data are comparable with the results of Aymar et al., who described participation in an educational intervention for pain management by 86.4% of the professionals in their analysis (Aymar et al., 2014).

This study has a few limitations. The basis of the study was a long-term observation period of 3 years to identify sustained changes, but the influence of other factors (e.g. changes in staff and administration) could not be ruled out. The findings of this study may not be generalizable, given the lack of patient randomization for the data entry form and the lack of a control group. We believe, however, that the study design, and particularly the long intervention period with repeated training sessions and conceptual changes, created a change in pain culture that encouraged the medical staff to be mindful of pain during daily activities and to think about pain management as a priority task. Strategies for improving paediatric pain management need further development, as Czarnecki et al. found in their 3-year reassessment study of nurses' perceptions of barriers to paediatric pain management. They found that the most significant barriers continued to involve delays in the availability of medications, insufficient medication orders by physicians, and insufficient orders and time allowed to pre-medicate patients before procedures (Czarnecki et al., 2014).

5. Conclusion

In conclusion, we achieved significant improvement in postoperative pain management in children by expending a tolerable amount of effort on interventions and training of health care professionals. Our results emphasize that it is important to take an interdisciplinary approach to pain management training and to use practical implementations of pain therapy strategies.

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Author contributions

M.H. and F.H. designed and managed the study, planned analysis, drafted manuscript, extracted and analysed data. A.M. managed the study, planned analysis, extracted and analysed data. All authors discussed the results and commented on the manuscript. All authors approved the final version.

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Conscious Sedation: Off-Label Use of Rectal S(+)-Ketamine and Midazolam for Wound Dressing Changes in Paediatric Heat Injuries

Abstract

Background: Wound dressing changes after heat injuries expose the patient to repeated painful and frightening procedures in short intervals. Safe, adequate, and easily administered analgesia and sedation are required. The goal of this study was to evaluate the off-label use of rectally administered S(+)-ketamine and Midazolam by paediatric surgeons during repeated outpatient dressing changes for paediatric burns and scalding.
Patients and Methods: A total of 47 dressing changes of 30 children with I – IIa° burns were evaluated. Vital signs, side-effects, complications, anxiolysis, and analgesia were recorded during the procedure and for the following two hours. Patients were assessed by a discharge scoring system and an age-appropriate pain scoring system at regular intervals. Before discharge, parents were interviewed on their level of satisfaction with the protocol.
Results: Adequate sedation and analgesia was achieved in 44 procedures (94%). No complications and, in particular, no compromise of breathing, ventilatory, and cardiovascular functions were recorded. The discharge scoring system indicated a return to baseline function 30 minutes after the procedure in all patients. The parents were generally very satisfied with the protocol. All children old enough to be questioned were found to have an anterograde amnesia for the duration of the procedure.
Conclusion: Conscious sedation with rectally applied S(+)-ketamine and Midazolam allows safe and painless dressing changes after heat injuries in children.

Key words
Conscious sedation · child · ketamine · ambulatory surgical procedures

Résumé

But: Le changement de pansement après brûlures expose les patients à des gestes douloureux, à de courts intervalles. Une analgésie sûre, adéquate et facilement administrée est nécessaire. Le but de cette étude est d'évaluer l'utilisation de Kétamine administrée par voie rectale et de Midazolam pour ces patients.
Patients et Méthodes: Un total de 47 changements de pansements chez 30 enfants avec des brûlures de degré I – IIa ont été évalués. Les signes vitaux, les effets secondaires, les complications, la diminution d'anxiété et l'analgésie ont été analysés durant ces pansements et pendant les deux heures qui ont suivi. L'intérêt était apprécié, par un score de douleur adapté à l'enfant, à intervalles réguliers. Avant la sortie, les parents étaient interrogés sur le niveau de satisfaction avec ce protocole.
Résultats: Une sédation adéquate et une analgésie étaient obtenus dans 44 pansements (94%). Aucune complication et, en particulier, aucune altération de la ventilation et de la fonction cardiovasculaire n'étaient observée. Le retour à une fonction normale était obtenu après 30 minutes chez tous les patients. Les parents étaient satisfaits du protocole. Les enfants suffisamment âgés étaient questionnés et avaient une amnésie de la durée du pansement.
Conclusions: Une sédation consciente avec de la S(+)-Kétamine injectée par voie rectale et du Midazolam permet des changements de pansements sûrs et sans douleur après brûlure chez l'enfant.

Mots-clés
Sédation consciente · enfant · kétamine · chirurgie ambulatoire

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Resumen

Objetivo: Los cambios de apósito tras las quemaduras exponen al paciente a repetidos procedimientos dolorosos y alarmantes. Son precisas una analgesia y una sedación seguras, adecuadas y de fácil administración. El objetivo de este estudio fue evaluar el uso de Ketamina y del Midazolan administrados rectalmente por el propio cirujano pediatra para los cambios de apósito en niños quemados.
Pacientes y Métodos: Se evaluaron 47 cambios de apósito en 30 niños con quemaduras de 1° o 2°. Se recogieron los signos vitales, los efectos colaterales, complicaciones, ansiolisis y analgesia durante el procedimiento y las dos horas subsiguientes.
Se evaluaron los pacientes en el momento del alta con un sistema de puntuación al alta y a intervalos regulares con una escala de dolor adecuados a la edad. Antes del alta se entrevistó a los padres sobre su satisfacción con este protocolo.
Resultados: Se obtuvo analgesia y sedación adecuadas en 44 procedimientos (94%). No hubo complicaciones y en particular no se observó ningún compromiso de la vía aérea, ventilación o función cardiovascular. El sistema de puntuación al alta indicó un retorno a la función basal 30 minutos tras el procedimiento en todos los pacientes. Los padres estuvieron en general muy satisfechos con el protocolo. Todos los niños suficientemente mayores para ser interrogados relataron una amnesia anterógrada durante toda la duración del procedimiento.
Conclusión: La sedación consciente con Ketamina-Midazolan aplicada rectalmente permite cambios seguros e indoloros de los apósitos tras las quemaduras en niños.

Palabras clave
Sedación consciente · niño · ketamina · procedimiento quirúrgico ambulatorio

Zusammenfassung

Hintergrund: Verbandswechsel bei Verbrennungen und Verbrühungen bedeuten für den Patienten wiederholt schmerzhafte und angsteinflößende Eingriffe in kurzen Zeitabständen. Eine sichere, adäquate und leicht zu applizierende Analgesie und Sedierung ist wünschenswert. Das Ziel dieser Studie war die Evaluierung von rektal verabreichtem Ketamin-S(+) und Midazolam für wiederholte Verbandswechsel bei Kindern durch den behandelnden Kinderchirurgen.
Patienten und Methodik: Im Rahmen einer prospektiven Studie wurden 47 Verbandswechsel bei 30 Kindern mit I-IIa° Verbrennungen oder Verbrühungen untersucht. Ausgewertet wurden die Vitalparameter, Nebenwirkungen, Komplikationen, Anxiolyse und Analgesie während der Eingriffe und des anschließenden zweistündigen Überwachungszeitraumes. Die Patienten wurden anhand eines Entlassungs-Scores (Aldrete discharge score, ASS) und einer altersentsprechenden Schmerzeinschätzung in regelmäßigen Abständen beurteilt. Vor der Entlassung wurde die Zufriedenheit der Eltern mit einem Fragebogen evaluiert.
Ergebnisse: Eine adäquate Sedierung und Analgesie konnte bei 44 Eingriffen erreicht werden (94%). Es traten keine Komplikationen, insbesondere keine Beeinträchtigung der Atemwege oder des kardiovaskulären Systems auf. Der Entlassungs-Score (ASS) zeigte schon 30 Min. nach dem Eingriff bei allen Patienten eine Entlassungsfähigkeit an. Die Eltern waren insgesamt sehr zufrieden mit dem Ablauf der Verbandswechsel. Alle Kinder, die alt genug waren, Angaben zu machen, gaben eine anterograde Amnesie für die Dauer des Eingriffes an.
Zusammenfassung: Eine „conscious sedation" mit rektaler Medikamentenapplikation von Ketamin-S(+) und Midazolam ermöglicht eine sichere und schmerzfreie Durchführung des Verbandswechsels nach Verbrennungen oder Verbrühungen bei Kindern.

Schlüsselwörter
Analgosedierung · Kinder · Ketamin · Midazolam · ambulante Behandlung

Introduction

Adequate sedation and appropriate anaesthesia are necessary to reduce anxiety during repeated painful procedures in children. It is well known that repetitive pain stimuli in young patients may lead to chronic pain syndrome (12). Current studies still demonstrate that paediatric patients receive inadequate pain medication (23,29). Adequate analgesia, on the other hand, decreases the stress response and may aid in wound healing (10,18).

Low-grade heat injuries in children often require repeated painful dressing changes, mostly performed in an outpatient setting. The majority of these procedures are performed by surgeons without the aid of a paediatric anaesthesiologists, for both economic and logistical reasons. Analgesia is usually administered in the form of single peripheral analgesic medication such as nonopoid analgesics including acetaminophen or NSAIDs, or children receive sedation alone. For invasive diagnostic or minor surgical procedures the American Society of Anaesthesiologists recommends a combination of a sedative and analgesic medication (3). Drug selection must take the patient's particular risk factors into account and the length and nature of the procedure. The most popular drugs here are ketamine together with benzodiazepines. In our paediatric surgery department we implemented a conscious sedation protocol using an off-label use of rectal S(+)-ketamine and Midazolam for painful procedures in children. In a previous pilot study 30 of these procedures were performed under the direct supervision of a paediatric anaesthesiologist in 22 children.

S(+)-ketamine was introduced for clinical use in childhood in 1998 (16). Compared to its racemic predecessor, S(+)-ketamine requires half the dose because the inactive R(-)-enantiomere is eliminated, thereby decreasing unwanted side effects such as bizarre hallucinations, nightmares, and dysphoria on awakening (8,22). Midazolam has been shown to provide amnesia during

painful procedures in children (28) and therefore was used in combination with S(+)-ketamine. Both drugs allow a rapid recovery and return to baseline (11,21).

Rectal administration of analgetic medication has specific advantages in the paediatric patient population: 1) The need for intravenous access is avoided, sparing the child this initial painful procedure; 2) exact doses are facilitated in comparison to the oral route, because the child cannot spit out or vomit the often unpalatable medication.

In this study, we prospectively examined our patients using rectally administered S(+)-ketamine and Midazolam to improve pain therapy during dressing changes for paediatric heat injuries in our outpatient paediatric surgery clinic. We focused on a single indication for this study to build a homogenous patient group and to reduce concomitant influences and bias.

Patients and Methods

Prospectively, children with I-IIa degree burn and scalding injuries covering 5 – 15 % of body surface were included in this study. All patients had to be healthy and classified as category one according to the ASA (American Society of Anaesthesiologists) (5). Current fasting guidelines were strictly observed (4): no clear liquids for two hours, no breast milk for four hours, and no formula, non-clear liquids or solids for six hours prior to the procedure. Preoperatively informed consent was obtained from the parents. The procedures were performed in our ambulatory operating suite with a suction device and resuscitation equipment available at all times. The patients were monitored for blood pressure, EKG, and arterial transcutaneous oxygen saturation until two hours after the procedure. The children received 0.75 mg/kg S(+)-ketamine and 0.4 mg/kg Midazolam rectally 20 minutes before the intended procedure. The procedure was started when the paediatric surgeon noted sufficient moderate sedation of the patient: state of depressed consciousness in which patients respond purposefully to verbal commands, either alone or accompanied by light tactile stimulation (13). The time of onset was documented. The levels of sedation and analgesia were graded by the paediatric nurse: 1) analgesia and sedation excellent: the patient was sleeping and immobile; 2) analgesia and sedation good: the patient showed some restlessness, but no crying; 3) insufficient analgesia and sedation: patient was crying. Continuous oxygen saturation was used for postoperative monitoring. At 15, 30, 60, and 120 minutes postoperatively, the heart rate, blood pressure, and oxygen saturation were documented. At these monitoring intervals, pain was assessed by age-appropriate scoring systems (KUSS [7] up to 4 years of age, Smiley/VAS [31] 5 years and older) and the children were evaluated by the discharge scoring system ASS (Aldrete Scoring System), which scores the patient's vital signs and psychomotor skills. If the patient's score after recovery indicates a return to baseline function (Score of 10), the patient is ready for discharge (Table **1**) (1,2). After two hours of observation, the patients were discharged by the paediatric surgeon with appropriate instructions to the parents with respect to possible adverse effects of the conscious sedation. Before discharge, satisfaction of the parents was assessed by a questionnaire based on VAS (Visual Analogue Scale 1 – 10): 1) satisfaction with the pain therapy; 2) satisfaction with the setting; 3) remarks. Children older than 6 years were asked about their satisfaction with the pain therapy as well as their antegrade amnesia for the duration of the procedure.

Table **1** Discharge Scoring System: Aldrete Scoring System (ASS)

Activity	
Can move voluntarily or on command	
– *4 extremities*	2
– *2 extremities*	1
– *0 extremities*	0
Respiration	
– *can breathe deeply and cough freely*	2
– *dyspnea, shallow or limited breathing*	1
– *apneic*	0
Circulation	
Preoperative BP (mmHg)	
– *BP ± 20 mm Hg of baseline*	2
– *BP ± 20 – 50 mm Hg of baseline*	1
– *BP ± 50 mm Hg of baseline*	0
Consciousness	
– *fully awake*	2
– *arousable on calling*	1
– *not responding*	0
Colour	
– *normal*	2
– *pale, dusky, blotchy*	1
– *cyanotic*	0

Results

Over a period of 14 months, 47 procedures in 30 children (aged 10 months to 7.3 years, mean 1.9 years) with I-IIa degree burn and scalding injuries covering 5 – 15% of body surface area were analysed in this study. Mean duration of the procedures was 9.6 minutes (range 3 – 15 minutes, median 10.1 minutes) and the time of onset was 16.5 minutes (range 5 – 30 minutes, median 15.3 minutes). In the immediate postoperative period, the ASS score after recovery indicated a return to baseline function in 75% of patients (ASS score of 10), and in all patients after 30 minutes. To be on the safe side, we observed the children for two hours before discharge in this study. The vital signs remained stable within the age-dependent normal values during and after the procedure. Compared to the preoperative values, no changes in blood pressure in excess of ± 15%, or changes in oxygen saturation of more than ± 3% were noted. All children managed to independently maintain their breathing without compromised ventilation at all times. The level of sedation and analgesia was excellent during 40 procedures and good during 4 procedures, in which the children showed slight restlessness without crying during the dressing change. Pain was documented in 3 patients during the procedure. Altogether, adequate sedation and analgesia was achieved in 44 procedures (94%). All patients were free of postoperative pain, and had 0 points in the pain scoring system during the whole postoperative monitoring time (Table **2**). All

Table 2 Results of rectally applied S(+)-ketamine and Midazolam during repeated outpatient dressing changes in paediatric heat injuries: Conscious sedation during 47 changes of wound dressing in 30 patients

Sedation + analgesia excellent	40 procedures (85 %)
Sedation + analgesia good	4 procedures (9%)
Insufficient analgesia	3 procedures (6 %)
Postoperative pain	0 procedures (0 %)
Alteration of blood pressure	± 15% of the basic value (0%)
Alteration of the heart rate	± 10% of the basic value (0%)
Alteration of oxygen saturation	± 3% of the basic value (0%)

children old enough to be questioned (n = 12) were found to have an anterograde amnesia for the duration of the procedure. Parents and children were generally very satisfied with the pain therapy (mean VAS = 9.1) and the sedation/analgesia protocol (VAS = 8.9). Minor complaints were raised by 5 parents because of the perceived long fasting times.

Discussion

Pain management is an important aspect in paediatric surgery. However paediatric health care professionals have the moral obligation to sufficiently and adequately manage pain resulting from the procedures they perform. Several recent studies have documented that pain in children is still underappreciated and undertreated (6,27,29).

Repeated dressing changes after low grade heat injuries performed only with oral peripheral analgesic medication such as nonopoid analgesics can cause a great deal of pain and anxiety in children. Nor is a sedative alone sufficient in such cases. The American Society of Anaesthesiologists therefore recommends a combination of a sedative and analgesic medication: the conscious sedation (3) is defined as "a medically controlled state of depressed consciousness that 1) allows protective reflexes to be maintained; 2) retains the patient's ability to maintain a patent airway independently and continuously; and 3) permits appropriate response by the patient to physical stimulation or verbal command, e.g., "open your eyes" (4). The advantages of using a conscious sedation protocol are a well documented safety profile if certain standards for monitoring are met, antegrade amnesia if Midazolam is used for sedation, and an adequate level of analgesia for most interventions. Generally, conscious sedation can be administered by a physician skilled in resuscitation in children for ASA classes one and two (4,20,25). In our opinion, alternative pain therapy with single peripheral analgesic medication, sedation alone, or deep sedation/analgesia for wound dressing in paediatric heat injuries I–IIa° would either represent over- or undertreatment, respectively. In our prospective study, the paediatric house officers performed and monitored the conscious sedation protocol by themselves in an appropriate surrounding.

While most protocols for conscious sedation use oral or intravenous routes for drug administration, the choice of rectal administration has distinct advantages: firstly, no intravenous cannula has to be placed before the procedure, which in itself can cause apprehension and stress in a child and seems to be too invasive for these procedures. Compared to the oral route, the time of onset is quicker and there is a lower first pass effect (14). The medication cannot be spit up by the child either, increasing dose accuracy. Disadvantages are the lower bioavailability compared to intravenous administration, and a broader variability in pharmacokinetic and pharmacodynamic parameters (14). Fortunately these drawbacks do not affect the usefulness for conscious sedation.

Our selection of S(+)-ketamine rather than the racemic mixture was based on the better safety and side-effect profile of the substance. Compared to the racemic mixture, S(+)-ketamine exhibits twofold greater analgesic and hypnotic potencies with a markedly shortened recovery time (30). In another study, S(+)-ketamine induced less tiredness and cognitive impairment than the equianalgesic racemic ketamine (24). These advantages seemed particularly important in children. In general, S(+)-ketamine produces a dissociative state with good analgesia, amnesia and sedation, but with the maintenance of spontaneous ventilation. Side effects are increased oral secretion, which can be reduced by simultaneous use of glycopyrrolate, as well as unpleasant emergence reactions, including hallucinations and nightmares (20). The concurrent use of benzodiazepines mitigates these psychotropic complications (9,13,17). Midazolam has replaced diazepam as the most popular drug for sedation in children (26). It produces anxiolysis and amnesia. Further advantages of Midazolam are the reduced interference in the haemodynamic system and the minimal irritation of the bronchial system (19). Both drugs are short-acting with a very rapid time of onset and a short half-life. However, the main risk in the application of midazolam is overdosage, which can depress ventilation (13,15), so that appropriate equipment for resuscitation must be available.

The perioperative monitoring of our patients showed no side effects, no depression of ventilation or influence on the vital signs using this protocol. After 30 minutes, all patients achieved 10 points in their ASS, technically permitting their discharge from the hospital. As mentioned before, the study protocol mandated postoperative monitoring for two hours for extra safety. In future, however, it may be possible to reduce this time. Pain assessment is routinely performed postoperatively in our ambulatory paediatric surgery clinic. No postoperative pain was detected with our conscious sedation protocol using a validated measurement by KUSS and Smiley/Visual Analogue Scale.

Conclusion

Conscious sedation in children using rectally S(+)-ketamine and Midazolam can be safely performed in an outpatient setting for dressing changes in lowgrade burn and scald wounds, providing that the contraindications are respected, drugs are given in a standardised dosage, and appropriate monitoring is assured. Postoperative monitoring should be performed for at least 60

minutes. The advantages are an appropriate sedation and analgesia in a co-operative patient with stabile vital signs. This protocol has produced a high level of satisfaction in children, parents, and healthcare workers.

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Self-Administered Procedural Analgesia Using Nitrous Oxide/Oxygen (50:50) in the Pediatric Surgery Emergency Room: Effectiveness and Limitations

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Abstract

Introduction Minor surgical interventions in children are often at times challenging due to the lack of cooperation by the child. Procedural sedation and analgesia is often appropriate, but unpleasant or painful applications of medication add additional discomfort to the child. A mixture of nitrous oxide (N_2O)/oxygen (O_2) in a ratio of 50:50, functioning as an inhalational sedative analgesic, may be a viable alternative, in particular in an emergency care setting because such mixtures require no fasting period and are self-administered. Therefore, in this study we investigated the feasibility and the effectiveness of N_2O/O_2 (50:50) as a sedative analgesic when performing minor surgical procedures.

Patients and Methods Procedural sedation and analgesia with an N_2O/O_2 (50:50) mixture applied during minor surgical procedures were prospectively evaluated over 2.5 years in a major pediatric hospital in Germany. Indications for sedation were either minor painful interventions, the injection of a local anesthetic, or a digital block in an emergency care setting. Diagnosis, type of surgery, inhalation time, complications, side effects, pain scores, and the child's behavioral reaction were assessed.

Results A N_2O/O_2 (50:50) mixture was administered in 210 children, ages 2.7 to 16.5 years (mean 9.0 years). Three treatments were terminated because of lack of compliance, nausea, or dizziness. No other side effects were encountered. During the intervention, 80.5% of all patients were pain free, and 81.9% were relaxed and calm. A higher rate of insufficient pain control was observed when the indication was an injection of a digital block or a reposition of fractures and dislocations.

Conclusions The use of self-administered N_2O/O_2 (50:50) mixture for minor painful procedures in children is safe and adequate pain control can be achieved in most cases. The benefits of this approach for the child and its parents are its good acceptance and adequate pain control. The benefit for the health care provider is the lack of a fasting period before administration, good anxiolysis at minimum sedation, and a cooperative

Keywords
- nitrous oxide
- children
- inhalation route
- pain
- minor surgery

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patient. Limitations are unsatisfying analgesia in some cases. Though not found in our study, potentially serious adverse events are a possibility and standard safety guidelines for minimal sedation should always be applied.

Introduction

Minor surgical interventions in an outpatient or emergency care setting in children are often challenging because the children rarely cooperate and suffer significant distress. A negative effect on the behavioral development of children undergoing painful or distressing medical or surgical treatments has been proposed.[1–3] Despite many recent improvements, pain control in children is often at times inadequate during painful procedures in the emergency room.[4,5]

Recommendations of expert commissions,[6] guidelines of anesthesia,[7] and systematic studies[8,9] are available for the management of analgesic sedation in children. The choice of medication for procedural sedation and analgesia depends on the procedure and the child's individual requirements. The most reliable method is intravenous administration, which provides a safe and quick sedation and analgesia. Oral, nasal, or rectal administrations are less invasive, but have less reliable absorption and attainment of analgesic dosage. Children often suffer additionally from painful needle puncture or other unpleasant application of pain control, such as rectal applications. Inhalational pain control, such as the mixture of nitrous oxide (N_2O)/oxygen (O_2) in a 50:50 ratio, has been proposed to be a viable alternative.[10] In the present article, we studied the self-administered application of an N_2O/O_2 (50:50) mixture in a single pediatric surgery department and focused on its effectiveness, safety, and limitations.

Patients and Methods

Procedural sedation and analgesia with an N_2O/O_2 (50:50) mixture (LIVOPAN, Linde Healthcare, Germany) were conducted independently by pediatric surgeons in the emergency department of our university hospital. The sedations were monitored and documented with the help of a standardized protocol, designed specifically for this study. After approval from the ethics committee of our faculty was obtained, a prospective evaluation was performed from October 2010 to April 2013. Indications for analgesic sedation with a N_2O/O_2 (50:50) mixture were the injection of a local anesthesia or a digital block (deep local nerve block) for wound care or minor surgical procedures and other painful interventions in an emergency care setting. No fasting period is needed for the application of the N_2O/O_2 (50:50) mixture. The N_2O/O_2 (50:50) mixture was used without other analgesics, sedative drugs, or topical anesthetic. Only healthy patients, as per guideline of the "American Society of Anesthesiology (ASA Group 1)" were included in the study. Exclusion criteria were traumatic brain injuries, otitis media, bowel obstruction, gastrointestinal disorders, or facial lacerations. Moreover, only children who kept the mask independently and voluntarily were given sedation and analgesia with the N_2O/O_2 (50:50) mixture. Before the intervention, written consent was obtained from the parents after a verbal briefing about the intervention and procedural sedation and analgesia.

The interventions were conducted in the emergency department's operating room with continuous monitoring of oxygen saturation. Appropriate equipment was available for emergency intervention in cases of too deep sedation or the loss of airway. Equipment included age- and size-appropriate for airway management and venous access, appropriate physiologic monitoring, sufficient numbers of people to carry out the procedure and monitor the patient, medical supervision according to the guidelines for monitoring and management of pediatric patients during and after sedation for diagnostic and therapeutic procedures.[6,11] The N_2O/O_2 (50:50) mixture was administered via a mask with a demand valve by a team who has had institutional training in N_2O administration. Appropriate scavenging of gases and venting of the exhaust system was performed to reduce environmental N_2O concentrations. Despite these precautions, pregnant medical staff was elected not to participate in these interventions. The intervention was started after an inhalation time of 3 to 5 minutes. The following data was collected and analyzed:

- Diagnosis and the type of intervention;
- Assessment of pain before, during, and after the intervention through a self-assessment using the face scale of Hicks et al[12] with a score of 0 (no pain) to 10 (strongest pain);
- Evaluation of the child's behavior: "relaxed and calm," "crying," "shows defensive reactions" or "additional restraint needed";
- Inhalation time of the N_2O/O_2 (50:50) mixture;
- The lowest oxygen saturation during the application of the N_2O/O_2 (50:50) mixture; and
- Complications or side effects.

Statistical Analysis

Descriptive statistics (frequency, mean, and standard deviation) was used to summarize characteristics of the study sample. Chi-square test and student *t*-test was conducted to compare the pain score level, child behavior during procedure, and age between the different groups of procedures. A p-value < 0.05 was considered to indicate a statistically significant difference.

Results

The records of 210 patients were assessed. The mean age of the patients undergoing interventions was 9.0 years (2.7–16.5years). The N_2O/O_2 (50:50) mixture was used in 33 cases for injection of a digital block, for the administration of

Table 1 Procedures performed in 210 children under the N_2O/O_2 (50:50) mixture

Digital block ($n = 33$)	n (%)	Local anesthesia ($n = 104$)	n (%)	Other procedures ($n = 73$)	n (%)
Closure laceration	23 (69.7)	Closure laceration	91 (87.5)	Closure laceration	39 (53.4)
Osseal reduction	10 (30.3)	Needle puncture[a]	7 (6.7)	Osseal reduction	3 (4.1)
		Foreign body removal	6 (5.8)	Intravenous cannulation	3 (4.1)
				Abscess drainage	18 (24.7)
				Needle puncture[a]	10 (13.7)

[a]Hematoma, joint effusion.

local anesthetic in 104 cases, and for other interventions in 73 cases (►Table 1).

Inhalation of the N_2O/O_2 (50:50) mixture was for duration of 5 to 30 minutes, with an average of 10.8 minutes. The lowest values of oxygen saturation were 100 to 97% (mean value 99.1%). The intervention was terminated in two patients because of nausea or dizziness and in another patient at the onset of inhalation because of a lack of compliance. The mean values of the pain score before, during, and after the intervention are shown in ►Table 2.

In our group of patients, moderate pain (score of 4–7) was observed in 16.7% of the patients during the intervention under the N_2O/O_2 (50:50) mixture, and a strong pain (score 8–10) was observed in 2.9% of patients (►Table 3).

During the intervention, most patients were relaxed and calm (81.9%). Additionally, 73.8% of the children were pain free. Crying, signs of a defensive reaction, or the need for additional restraint during the application occurred in 18.1% of the cases. The distribution of these behavioral observations during the various interventions is shown in ►Table 4.

The number of patients that were both relaxed and calm as well as pain free during the intervention was 73.8% in the total cohort, 45.5% in the group with a digital block, 82.7% in the group with local anesthesia, and 75.3% in the group with other procedures.

The mean and standard deviation of the age of the patients in the different groups of procedures, pain scores, and child behaviors during the procedures is shown in ►Table 5. The mean age of the children who cried during the intervention, who showed defensive reaction or needed additional restraint was 8.0 years, which was lower than the age of the patients who were relaxed and calm during the intervention (9.3 years).

Except for the nausea or dizziness of the two patients mentioned above, which led to a termination of the

Table 2 The median and standard deviation of the pain scores before, during, and after the procedures under the N_2O/O_2 (50:50) mixture ($n = 207$)

Patients	Pain score (± standard deviation)		
	Before procedures	During procedures	After procedures
Total	1.4 (1.83)	2.1 (2.08)	0.4 (0.96)
Digital block	2.1 (1.65)	3.9 (2.52)	1.2 (1.40)
Local anesthesia	1.4 (1.85)	1.7 (1.90)	0.2 (0.48)
Other procedures	1.1 (1.82)	1.9 (1.67)	0.4 (1.08)

Note: Pain scores, self-assessment with the face scale of Hicks et al[12] with a score of 0 = no pain to 10 = strongest pain.

Table 3 Moderate (pain score 4–7) or strong pain (pain score 8–10) during the intervention under the N_2O/O_2 (50:50) mixture by groups of procedures ($n = 207$)

Patients	n	Rate of patients with	
		Moderate pain n (%)	Strong pain n (%)
Total	207	35 (16.9)	6 (2.9)
Digital block	33	15 (45.5) $p < 0.001$[a]	3 (9.1)
Local anesthesia	102	10 (9.8) $p = 0.01$[a]	2 (2.0)
Other procedures	72	8 (11.1) NS[a]	1 (1.4)

Abbreviation: NS, not significant.
[a]Chi-square test.

Table 4 Child behaviors during N_2O/O_2 (50:50) mixture by groups of procedures ($n = 207$)

Patients	Child behavior during procedure			
	Relaxed and calm *n* (%)	Crying *n* (%)	Defensive reaction *n* (%)	Additional restraints needed *n* (%)
Total	168 (81.9)	19 (9.5)	11 (4.8)	9 (3.8)
Digital block	21 (63.6) $p = 0.005$[a]	7 (21.2)	3 (9.1)	2 (3.8)
Local anesthesia	91 (88.5) $p = 0.003$[a]	5 (5.8)	2 (1.9)	4 (6.1)
Other procedures	56 (78.1) NS[a]	7 (9.6)	6 (8.2)	3 (4.1)

Abbreviation: NS, not significant.
[a]Chi-square test.

Table 5 Age of patients by groups of procedures, pain score, and child behaviors during the procedures under the N_2O/O_2 (50:50) mixture ($n = 210$)

Variable	Age of patients		
	Mean (y)	Standard deviation (±)	*p*-Value[a]
Procedures			
Total	9.0	3.21	
Digital block	9.9	3.90	0.23 (NS)
Local anesthesia	8.5	2.57	0.16 (NS)
Other procedures	9.4	3.60	0.40 (NS)
Pain score			
4–10	8.9	3.79	0.76 (NS)
0–3	8.7	3.16	
Child behaviors			
Relaxed and calm	9.3	3.21	0.02
Crying/defensive reactions/additional restraint needed	8.0	3.03	

Abbreviation: NS, not significant.
[a]Student's *t*-test.

intervention, no other complications or side effects were encountered. However, euphoria was mentioned explicitly in the documentation by three patients. An assessment of the different interventions demonstrated that the injection of a digital block was one of the most painful interventions, with an average pain score of 3.88. Pain scores of 1.69 for local anesthesia and 1.85 for other interventions were recorded. In 54.6% of the patients the pain score was > 3 during the onset of a digital block, in comparison 11.5% of the patients with local anesthesia, and 12.4% of the patients with other procedures the pain score was higher than 3.

Discussion

Our goal was to analyze our own results regarding mild sedation using an N_2O/O_2 (50:50) inhalational mixture in a pediatric surgery population during painful interventions. We show that this type of mild analgesia and sedation is both safe and useful.

The inhalational application is more pleasant than nasal, rectal, or intravenous administration for many children.[10,13] At a concentration of 50% nitrous oxide, the circulatory function normally remains unaffected and spontaneous respiration and respiratory reflexes remain intact. In a study by Gall et al,[14] respiratory or cardiovascular complications occurred in 0.3% of the patients when the N_2O/O_2 (50:50) mixture was administered to children, but these effects were reversed immediately when the inhalation of 50% nitrous oxide was stopped. None of these patients needed invasive therapy. However, some patients also received benzodiazepine and opioids. In groups of patients, in which only the N_2O/O_2 (50:50) mixture was administered, no respiratory and cardiovascular problems have been noted.[10,15,16] Other side effects, such as euphoria, nausea, vomiting, or dizziness, have been observed in 5 to 16% of patients.[14,16] In our group of patients, nausea or dizziness occurred in just two patients (1.0%), euphoria in three patients (1.9%), and no other

complications or side effects were observed. Termination of the intervention was necessary in three cases (1.4%); in two cases because of nausea or dizziness, and in one case due to a lack of compliance. This failure rate is consistent with the results of Zier et al.[17] In their study interventions could not be completed in 0.9% of the cases. Zier et al found less minor adverse events include nausea (1.6%), vomiting (2.2%), and diaphoresis (0.4%) in their study, which included 7,802 cases of nitrous oxide administration.[18] Nine patients had potentially serious events such as brief oxygen desaturation but no apnea or brief generalized tonic-clonic seizure activity. All patients recovered without further incidents.[18] The reported severe adverse events occurred all in children receiving inhaled N_2O in concentration > 50% up to 70%. There was no correlation between age and adverse events.[18,19] But there was an increased incidence of adverse events with more than 15 minutes of administration time of N_2O, and four of the nine patients had additional health issues such as gastroesophageal reflux disease, epilepsy, or tracheostoma.[18] Therefore, N_2O for procedural sedation and analgesia in a maximum concentration of 50% seems more adequate for the use in children. In their guidelines for monitoring and management of pediatric patients during and after sedation for diagnostic and therapeutic procedures, the American Academy of Pediatrics (AAP) defined the use of N_2O for minimal sedation as the administration of N_2O 50% or less without any other sedative, narcotic, or other depressant drug before or concurrent with the N_2O to an otherwise healthy patient American Society of Anesthesiologists (ASA) class I or II.[7] Nonetheless, rigorous screening for specific contraindications to N_2O administration, potential contraindications to sedation, and presence of additional health issues or features that might place them at risk for airway compromise during sedation is essential.[18] Most importantly, with respect to the application of the N_2O/O_2 (50:50) mixture, there seems to be no risk of obtaining dangerously deep sedation. The degree of sedation under a 50 to 70% nitrous oxide concentration is minimal (score of 5),[17] according to the Children's Hospital of Wisconsin Sedation Scale.[20] This is in accordance with the findings of our study. We did not observe a single case in which sedation affected vital organ functions. Nevertheless, monitoring of physiological parameters and functions and adherence to standard guidelines for procedural sedation are necessary for patients with administration of N_2O/O_2 (50:50) mixture.[11,21]

Beside the adverse effects of N_2O mentioned above, other significant physiological effects from repeated or long-term administration of N_2O have been described.[21] Concern has been expressed regarding the chronic exposure of health care workers to N_2O. Chronic exposure may lead to infertility or increased rates of spontaneous abortion as well as possible adverse effects on the bone marrow and the central nervous system.[21,22] Therefore, appropriate scavenging of gases, proper functioning of the delivery apparatus, adequate ventilation of the procedural area, venting of the exhaust system, and effective mask fit on the patient is recommended to reduce environmental N_2O concentration and to ensure that excessive occupational exposure does not occur.[21] For this reason, we used a face-mask system with demand valve for gas delivery, not a dental "nasal" mask, where room air may be entrained resulting in increased N_2O concentration.[21] Also, in our current setup, pregnant medical staff does not participate in these interventions.

The indication for the application of the N_2O/O_2 (50:50) mixture in our group of patients was the injection of a local anesthetic for wound care in 73% of the cases. To perform this procedure, in most of the children's hospitals in Germany, no additional sedation and analgesia are routinely administered in an emergency care setting. Children that are not compliant often get restrained to receive injection of local anesthetics, and must therefore endure not only pain from the injection but also a significant amount of fear and bodily distress. By using additional analgesic sedation with the N_2O/O_2 (50:50) mixture, in our study this could easily be avoided. This was especially attractive from the providers' point of view because the N_2O/O_2 (50:50) mixture can be applied easily without a fasting period and without the help of an anesthesiologist. The N_2O/O_2 (50:50) mixture has been successfully used for venous punctures by others.[13,16] The advantage lies in the attainment of better analgesia and additional anxiolysis compared with EMLA (eutectic mixture of local anesthetics; Astra Zeneca GmbH, Wedel, Germany).[23] The anxiolytic effect is certainly the decisive factor for the use of the N_2O/O_2 (50:50) mixture for the injection of local anesthesia. A significant reduction in the anxiety level score and the pain score has been shown in a prospective, randomized, placebo-controlled, and double-blinded study of wound care in children.[13]

Additionally to the interpretation of pain scores, the effectiveness of an analgesic sedation can be assessed through the evaluation of the patient's behavior, his level of distress, a pain assessment, and the degree of sedation.[3,24] In our study, the effectiveness of the N_2O/O_2 (50:50) mixture with respect to those patients that during the intervention were both "relaxed and calm" as well as "pain free" was 73.8% in the total cohort and varied between 82.7% in the group with local anesthesia and 45.5% in the group with digital block. Other studies have indicated a somewhat better effectiveness of 80.0 to 94.1%.[16,17] However, in these previous studies, a higher concentration of nitrous oxide of 60 to 70% was used. Ozil et al evaluated pain and comfort of the patients by the use of a behavioral score and only 45.5% indicated no pain related behavior during the treatment of burn lesions.[25] Pain under the N_2O/O_2 (50:50) mixture has been assessed in most previous studies using a visual analogue scale[10,15,24,26] or, like in our study, using a self-assessment of the face scale of Hicks et al.[12,16,27] Our data showed that N_2O/O_2 (50:50) mixture was effective for the relief of pain for minor surgery in emergency care, particularly for laceration repair, puncture, reposition, and abscess drainage. Similarly, Burnweit et al have reported almost pain-free surgery in minor excisions and the drainage of abscesses using an N_2O/O_2 (50:50) mixture analgesia.[28] In our group of patients, pain scores of 4 to 10 appeared during the intervention in 19.6% patients. Previous studies have observed higher values of 25 or 34%.[26,27] A higher rate of pain score was observed when

the indication was an injection of a digital block as well as a reposition of fractures and dislocations. The latter results have been shown in a study by Babl et al[26] and concluded that exclusive procedural sedation and analgesia with an N_2O/O_2 (50:50) mixture was not adequate for the reduction of fractures and dislocations, even if these dislocations were only marginal. Injection of a digital block is routinely done with no further sedation and analgesia. However, our data show that the injection of a digital block was one of the most painful procedures, and additional procedural sedation and analgesia should be used to increase patient comfort in such situations, especially if the patient is a child.

The evaluation of the effectiveness of an analgesic sedation can include an assessment of pain and the assessment of the patients' behavior regarding distress. Behavior-based pain or distress scores for children, such as CHEOPS (Children's Hospital of Eastern Ontario Pain Scale)[29] or OSBD (Observation Scale of Behavioral Distress)[30] have not been validated adequately for painful procedures.[25] These scores have been used previously in individual studies with a small number of cases (n = 34–36).[27,31] In two publications with larger number of cases (n = 975 and 2,045), the assessment of behavior was performed using a simple evaluation based in a yes/no response to the following reactions: relaxed and calm, crying, agitated and defensive reactions, and additional restraint needed.[10,17] In the work of Annequin et al, crying, defensive reactions or additional restraint needed was indicated in 8.4 to 44.1% of patients under analgesia with the N_2O/O_2 (50:50) mixture.[10] In our group of patients, this behavior appeared in 1.9 to 21.2% of patients. However, the mean age of patients in Annequin et al's study was lower compared with ours by approximately 3 years. Our data show that the mean age of the patients who are relaxed and calm during the procedure was 9.3 years. Therefore, it seems that school age is favorable for the use of the self-administered N_2O/O_2 (50:50) mixture.

Conclusion

In conclusion, our study confirms that the application of the N_2O/O_2 (50:50) mixture during minor therapeutic procedures by the pediatric surgeon was safe. Standard sedation guidelines for minimal sedation definitely apply because potentially serious adverse events are always a possibility.[6] To minimize the risk of potential severe adverse events no more than 50% concentration N_2O should be administered, no equipment that delivers variable ratios of N_2O should be used and no additional sedative, narcotic, or other depressant drugs should be combined with N_2O. The use of face-mask system with demand valve is an additional prevention of loss of consciousness. Preferred indications for the N_2O/O_2 (50:50) mixture are the injection of local anesthesia or minor painful procedures in school-aged patients. Adequate pain control is possible in most patients in our study. Limitations can be an unsatisfying analgesia; especially if the indication is an injection of a digital block or the reduction of fractures and dislocations. The analgesic efficacy of N_2O/O_2 (50:50) mixture should not be overestimated. The benefits of this procedural sedation and analgesia were good acceptance and anxiolysis at minimum sedation and cooperative patients. The additional advantage is a fast and easy administration with a low-procedural planning, and the lack of needing a fasting period.

Conflict of Interest

None.

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ORIGINAL ARTICLE

Children and adolescents with ureteropelvic junction obstruction: is an additional voiding cystourethrogram necessary? Results of a multicenter study

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Abstract
Purpose The incidence of ureteropelvic junction obstruction (UPJO) and concomitant vesicoureteral reflux (VUR) ranges from 14 to 18 %. Therefore, different guidelines recommend a voiding cystourethrogram (VCUG) to identify cases of VUR early in the diagnostic process. Aim of this multicenter study was to reassess the incidence of concomitant VUR and the need for additional VCUG in a large cohort of patients with UPJO. Furthermore, we asked for clinical objectives that defined the need for VCUG with the intention of minimizing radiation exposure and the need for invasive diagnostic procedures.

Methods Medical records for 266 patients (69 girls, 197 boys) with UPJO were analyzed retrospectively. Data were obtained on gender, clinical symptoms, results of pre- and postnatal ultrasound, VCUG and ^{99m}Technetium-MAG3 (MAG3) scan. They were correlated with the incidence of concomitant VUR.
Results One hundred and seventy-eight patients (67 %) underwent VCUG. Concomitant VUR was detected in 13 patients. Dilating VUR (dVUR) was observed in 11 patients. In our study, the overall incidence of a concomitant VUR was 7.3 %. In cases of proven VUR, we observed a positive predictive value for female gender, ureteral dilatation, renal insufficiency, and recurrent urinary tract infections (UTI). But there was no correlation between concomitant VUR and the severity of hydronephrosis.
Conclusions Our data suggest that the low incidence of concomitant VUR in cases of UPJO does not justify the routine use of VCUG as a routine diagnostic tool. Especially, ureteral dilatation and recurrent UTI have a positive predictive value for concomitant VUR.

Keywords Ureteropelvic junction obstruction · Concomitant vesicoureteral reflux · Incidence

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Introduction

Ureteropelvic junction obstruction and vesicoureteral reflux are both common pathologies in childhood. The incidence for UPJO is 1:4,000 in newborns with a male-to-female ratio of 2.5:1 [1]. VUR is detectable in approximately 1 % of all children over 1 year of age. In addition, 30–40 % of children with febrile UTI have an underlying VUR. Females are three times more prone to VUR than males [2].

The coincidental appearance of VUR in the case of UPJO has previously been described, and these authors have reported on an incidence as high as 18 % [3–5]. Based on these data, recent guidelines suggest the routine investigation by VCUG to exclude a concomitant VUR [6–8]. However, from our experience, a VCUG is invasive and poorly tolerated by children and parents. In addition, VCUG is associated with exposure to ionizing radiation.

In our institution, the coincidence of UPJO and VUR was observed to be lower compared to other reports [3–5]. Therefore, the aim of this multicenter study was to assess the diagnostic value of VCUG in a large cohort of children and adolescents with UPJO. We also looked for other indicators of concomitant VUR that define the need for VCUG to the minimize radiation exposure and the need for invasive diagnostic procedures.

Materials and methods

Patients

We analyzed medical records of 266 patients (<18 years of age) with primary UPJO, treated between 01/2004 and 09/2009 in 4 different pediatric urologic centers in Mainz, Augsburg, Deggendorf, and Munich, Germany. The number of patients from a single center ranged from 40 to 102 patients.

Data acquisition

Data were obtained by medical chart review on gender, age at the time of diagnosis, degree of hydronephrosis and drainage pattern, reflux, localization of pathological findings, clinical symptoms, and any performed diagnostic procedures. A grading of the hydronephrosis was done according to the Society for Fetal Urology [9]. A classification of the VUR according to the International Reflux Study Committee (1985) [10] was not applicable because dilatation of the pelvis was due to the UPJO. Thus, we categorized the refluxes in non-dilating and dilating VUR (ndVUR and dVUR, respectively). The sonographic findings and VCUG were validated by experienced pediatric urologists.

UPJO was diagnosed by MAG3 after hydration and application of furosemide, according to the guidelines of the German society of Nuclear Medicine [11]. Patients with UPJO secondary to high-grade VUR and a kinking at the ureteropelvic junction were excluded from the study.

Diagnostic follow-up

Newborns with pathologic prenatal ultrasound findings underwent postnatal sonographic reevaluation. Other patients with clinical symptoms or incidental radiological findings suggestive for hydronephrosis also received an ultrasound of the urinary tract. In cases of first-degree hydronephrosis, the ultrasound was repeated after 6 weeks.

A MAG3 scan was performed in all cases of high-grade hydronephrosis. Criteria to perform a MAG3 were a pyelon dilatation >10 mm and a persistence or progression in follow-up ultrasounds. In most cases of verified UPJO, an additional VCUG was performed according to recent guidelines [6–8] to exclude a concomitant VUR. VCUG was always performed when clinical findings (i.e., UTI or ureteral dilation on ultrasound) were suspected for VUR. In the absence of such clinical signs, indication for VCUG was made individually and varied between the participating centers. Follow-up examinations were scheduled for a median period of 36 months (range 1.2–76 months).

The statistical analysis was performed in cooperation with the Institute of Medical Informatics, Biometrics, and Epidemiology, LMU Munich. Fisher's exact test was used to compare the different groups.

Results

The patient age ranged from prenatal to 17 years of age with a median age of 2.1 years. A total of 101 children were <1 year of age at the time of diagnosis (41 %). The male-to-female ratio was 3:1 ($m = 197$; $f = 69$) (Table 1). The diagnosis of hydronephrosis was made prenatally in 89 patients (33 %). Twenty patients (7.5 %) were identified <30th week of gestation.

Ureteropelvic junction obstruction

Hydronephrosis was detected predominantly on the left side (141 patients, 53 %). The right side was affected in 69 patients (26 %) and both kidneys in 56 patients (21 %). Thus, a total of 322 ureteral units in 266 patients had pathological results. All grades of hydronephrosis were equally represented. UTI was the primary clinical sign in 44 cases (17 %), but the vast majority of patients (70 %) did not suffer from any symptoms at the time of diagnosis. In those cases, hydronephrosis had either been suspected during prenatal ultrasound or was an incidental finding in abdominal ultrasounds performed for other reasons (Fig. 1). An associated retrovesical ureteral dilatation was observed in only 11 cases of hydronephrosis (4.1 %) (Fig. 2). However, the assessment of retrovesical ureteral dilatation was not performed in 57 cases (20.9 %). Scintigraphic obstructive drainage patterns were found in all 322 ureteral units. Five patients (2 %) had a renal partial function <10 % (Fig. 3; Table 1).

Table 1 Overview of the collected data

	Localisation	Symptoms	Ureteral dilatation	Drainage pattern in MAG3	Grade of hydronephosis
Whole cohort n = 266 m:f 3:1	Hydronephrosis right side n = 69 (26%)	**UTI n = 44 (17%)**	**Dilated ureter n = 11 (4.1%)**	> 45% drainage n = 189 (71%)	Grade I n = 51 (16%)
	Hydronephrosis left side n = 141 (53%)	No symptoms n = 188 (70%)	No dilatation n = 198 (74%)	10% - 45% n = 72 (27%)	Grade II n = 90 (28%)
	Hydronephrosis bilateral n = 56 (21%)	Pain n = 24 (9%)	**No assessment n = 57 (20.9%)**	< 10% n = 5 (2%)	Grade III n = 115 (36%)
	A total of 322UU	others n = 10 (4%)			Grade IV n = 62 (19%)
					unknown n = 5

	Concomittend VUR	Symptoms	Ureteral dilatation	Drainage pattern in MAG3
Patients with VCUG n = 178 (67%) m:f 6:7	**Concomittend VUR n = 13 (7.3%)**	**UTI n = 4 (31%)**	**Dilated ureter n = 3 (20%)**	> 45% drainage n = 8 (62%)
	bilateral VUR n = 5 (2.8%) A total of 18UU	No symptoms n = 9 (69%)	No dilatation n = 5 (40%)	10% - 45% n = 5 (38%)
	No VUR n = 165 (92.7%)		**No assessment n = 5 (40%)**	< 10% none

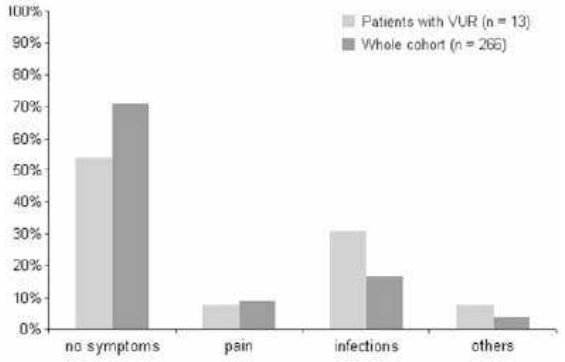

Fig. 1 Comparison of the symptoms for the whole cohort and those patients with a concomitant VUR. Patients with a VUR suffer from UTIs twice as often, but the results are not significant ($p > 0.05$). The data are displayed as *percentages*

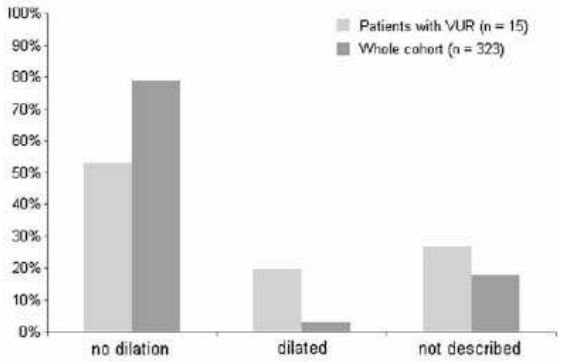

Fig. 2 The amount of dilated retrovesicular ureters in the whole cohort and in those patients with a concomitant VUR. Dilated ureters are detectable in 20 % of patients with VUR ($p < 0.01$). The data are displayed as *percentages*

Concomitant vesicoureteral reflux

One hundred and seventy-eight patients (67 %) underwent further VCUG. The ratio of performed VCUG ranged from 59 to 100 % in the participating centers. Concomitant VUR was observed in 13 patients (7.3 %), 5 of which were bilateral, 4 were uni- and 4 contralateral; therefore, 18 UU were affected. One-third of the UU had dVUR ($n = 6$). There was an equal distribution of VUR in both genders (m:$f = 1$:1.2). Thus, the percentage of female patients with a VUR and UPJO was 10.1 %, whereas this percentage was only 3.0 % in male patients ($p < 0.05$) (Fig. 4). With regard to the preponderance of males with UPJO, females might be at a higher risk to have a concomitant VUR.

UTI was the leading clinical sign in 4 patients with a VUR (31 %, $p > 0.05$) (Fig. 1), whereas 9 patients did not show any symptoms (69 %) (Fig. 1). Ureteral dilatation in ultrasound was detected in 3 patients with a VUR (20 %, unknown $n = 5$, $p < 0.01$) (Fig. 2). Finally, the ratio of obstructive drainage pattern in patients with a VUR did not differ from that of the whole cohort ($p > 0.05$) (Fig. 3). However, none of the affected patients had a loss of kidney function as defined by a partial function less than 10 % (Table 1), and none of those patients who did not underwent a VCUG were suspected for VUR during follow-up.

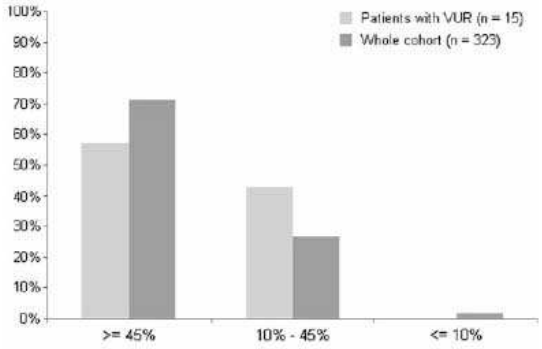

Fig. 3 Renal function of the affected kidney for all patients and those with a concomitant VUR. There are no relevant differences between the groups ($p > 0.05$). The data are displayed as *percentages*

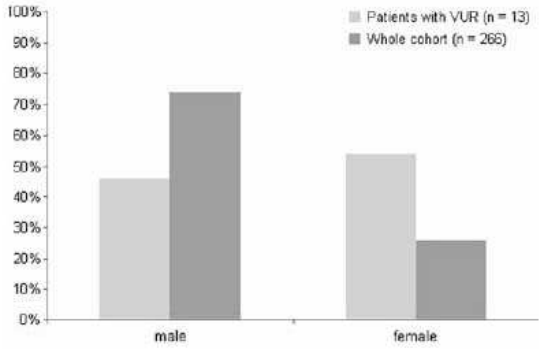

Fig. 4 Gender distribution. Females are at a higher risk for a concomitant VUR ($p < 0.05$). These results indicate a 10.1 % rate of incidence of VUR in female patients with UPJO versus 3.0 % in male patients. The data are displayed as *percentages*

Discussion

In the current literature, the data on coincidence of UPJO and VUR in childhood is limited [3–5, 12–16]. Bomalaski et al. and Lebowitz et al. [3, 15] described a coincidence for UPJO and VUR of up to 18 %. Based on these findings, recent guidelines suggest an additional VCUG in cases of detected UPJO [6–8]. The current version of the EAU guidelines (2012) advises to perform a VCUG in newborn with UPJO, but they do not define clear criteria for older children [17]. However, both authors did not look for concomitant VUR in their patients with UPJO. But they described those cases of VUR and UPJO with a coincidence in general. In our experience, the incidence of a concomitant VUR in the case of detected UPJO seems to be much lower. Therefore, we analyzed our patients with verified UPJO with a special regard for concomitant VUR but with the limitation of a retrospective study. In contrast to the above-described literature, this coincidence was verifiable in only 7.3 % of cases. In addition, two-thirds were cases of ndVUR with no need for surgical intervention. However, those patients required antibiotic prophylaxis and radiological reevaluation.

In a large clinical study, Mamì et al. [18] screened 11,801 healthy newborns for severe renal dilatation. They detected 46 cases (<1 %) with a relevant obstruction, but none had a concomitant VUR. This further demonstrates that the coincidence seems to be rare.

Furthermore, we looked for clinical signs that may indicate for VUR. Previous studies [19] and our data show that patients with a VUR were more likely to have UTIs (Fig. 1). However, the difference did not reach statistical significance due to the limited amount of patients and the different sizes of the patient groups. But the rate of UTIs was almost twice as high (31 %) in patients with a VUR compared to in the whole cohort (17 %). Although our results failed to reach statistical significance, the association of VUR and UTI is well known [19].

Patients with a VUR also had a detectable retrovesical ureteral dilatation in ultrasound more frequently. Ureteral dilatation was only observed in 3 % of all patients, whereas 20 % of those with a VUR showed this pathology ($p < 0.01$) (Fig. 2; Table 1). This, too, is a well-characterized association [20].

In addition, we noticed that in a high number of ultrasound examinations ($n = 57$, 20.9 %), no attention was paid to a possible ureteral dilatation. In our analysis, it stayed unclear why the retrovesical ureter was not assessed in every case. However, because ureteral dilatation has a positive predictive value for VUR [20], identifying this condition could be crucial for further decision making. Therefore, a thorough ultrasound examination should be performed with careful attention to a retrovesical ureteral dilatation.

The prevalence of concomitant VUR was higher in female patients ($p < 0.05$) (Fig. 4). This may be due to the increased predisposition for VUR, which is a well-known phenomenon [2]. Following this, female gender is another criterion for informed decision making. Additional criteria, such as the grade of hydronephrosis, were not distinctive predictive factors.

In another study, Estrada et al. [14] screened 1,514 newborns with prenatal detected grade 2 hydronephrosis. They detected a VUR in 28 % of those 1,150 patients who underwent a VCUG. Based on these findings, they estimated a risk of 4.4 % for UTI in those patients with hydronephrosis and made an ensuing recommendation for prophylactic antibiotics and a general need for VCUG in those infants [14]. In contrast to Estrada et al., Mamì et al. rejected this recommendation due to the scarcity of clinically relevant VUR in those patients with severe hydronephrosis [21]. However, our data suggest that the

probability of a concomitant VUR in patients with UPJO is much less than assumed. Similar findings were reported by Kim et al. [14], who found this coincidence in 6 % of the cases, as well as a correlation with a dilated ureter in ultrasound. Thus, they argued against a general need for VCUG in the case of UPJO. Our results support the findings of Kim et al. and characterize VCUG in the presence of UTI as obligatory.

Conclusion

Our study showed that there is no general need for a VCUG in patients with UPJO. However, certain clinical signs can help to identify those patients who require additional diagnostics. Those patients with ureteral dilatation detected by ultrasound and/or a UTI are at an especially higher risk for a concomitant VUR. In all other cases, there seems to be no indication for this invasive diagnostic procedure. Due to the retrospective nature of this work, our findings should be verified by a prospective study with a defined study design.

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Conflict of interest None.

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2000	Mitarbeit in der Abteilung für päd. Visceralchirurgie
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2002	Beauftragte für Qualitätsmanagement und Mitarbeit im Qualitätszirkel der bayrischen Kinderchirurgen
2003	Leitung des Manometrielabors für anorektale Funktionsdiagnostik
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2005	Facharzt für Kinderchirugie
2005	1st European Pediatric Urology In-Service Exam, ESPU, Regensburg
2005	Leitung des „Interdisziplinären Stuhltraining“ für Kinder mit Stuhlinkontinenz nach angeborenen Fehlbildungen
2006-2016	Leitung der päd. visceralchirurgischen Abteilung

2008	Herausgabe „Kinderchirurgie – Basiswissen und Praxis“ 1.Auflage (von Schweinitz, Heinrich, Neuhaus)
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2015	Kontinenztrainer für Kinder und Jugendliche, Essen
2015	Mitautor bei der Leitlinie AWMF „Enuresis und nicht-organische (funktionelle) Harninkontinenz bei Kindern und Jugendlichen
2016	Leitung der Kinderurologie
2017	Dezentrale Ethikbeauftragte der Kinderchirurgischen Klinik

Anleitung von medizinischen Doktoranden

2003-2006	Nadine Tillo: Endochirurgisches Trainingsmodell (Kaninchen) in der Kinderchirurgie - Etablierung und Studie zum Erlernen von Minimal-invasiven Techniken mit 12 Probanden.
2009-2014	Andra Mechea: Prospektive Interventionsstudie bei Kindern zur Optimierung der postoperativen Schmerzmanagements.
2010-2014	Dunja Föhlinger: Langzeitverlauf der Blasenfunktion bei 167 Kindern mit Meningomyelocele
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Lehrtätigkeit

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Inhouse Schulung „Schmerzmanagement bei Kindern“

Trainer pädiatrisches Simulationstraining Dr. v. Haunersche Kinderklinik

Allgemeine Kurse zur (Kinder-) Chirurgischen Weiterbildung:

Grund- und Aufbaukurs interdisziplinäre Ultraschalldiagnostik, Nürnberg, 1996 und 1997
Pädiatrische Dopplersonographie, periphere Gefäße und Bauchgefäße, Landshut, 2000

Kompaktkurs Notfallmedizin Stufen A – D, Berchtesgaden, 1997

Praktischer Kurs für gastroenterologische Chirurgie, Davos, 1998

Handkurs, Anatomie und frische Verletzungen, Wien, 1998

AO-Kurs – Prinzipien der operativen Frakturbehandlung, Davos, 1998

Paediatric Urodynamics, ESPU, Utrecht, 2001

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Klinisch-anatomischer Präparierkurs, LMU Anatomische Anstalt, 21.-23.10.2005

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Fortbildungsveranstaltung laparoskopische Fundoplikatio, Prof. Dr. R. Pointner, Zell am See, 28.-29.10.2001
IPEG Pediatric Surgery Fellow´s Advanced minimally invasive surgery hands-on workshop, Los Angeles, 2003

Minimally invasive techniques in paediatric Surgery (Curriculum III), European Surgical Institute, Hamburg, 2004

Intensivkurs "Laparoskopische Chirurgie", Strasbourg, 2006

Mitglied in Fachgesellschaften

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Smith Medical – 1.Kinderschmerzforum (2007)	300 Euro
Elterninitiative Intern 3 (2008) Schmerzkarte	1000 Euro
Hauner Verein (2015) Psychologenstelle TVL-12, Kinderchirurgie für 15 Monate (in Zusammenarbeit mit dem PD Dr. Hubertus)	35.000 Euro
Private Spende über Hauner Verein (2016) Zweckgebunden: Diagnostik MMC-Patienten	400 Euro

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