Evidence-based surgery: interventions in a regional paediatric surgical unit

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Abstract

Objectives—To determine the proportion of paediatric surgical interventions that are evidence-based and to identify areas where randomised controlled trials (RCTs) or further research are required.
Design—Prospective review of paediatric general surgical inpatients.
Setting—A regional paediatric surgical unit.
Subjects—All consecutive paediatric general surgical patients admitted in November, 1995.
Main outcome measures—Each patient on whom a diagnosis had been made was allocated a primary diagnosis and primary intervention (n=281). On the basis of expert knowledge, Plusnet Medline, and ISI Science Citation database searches, each intervention was categorised according to the level of supporting evidence: category 1, intervention based on RCT evidence; category 2, intervention with convincing non-experimental evidence such that an RCT would be unethical and unjustified; category 3, intervention without substantial supportive evidence.
Results—Of 281 patient interventions, 31 (11%) were based on controlled trials and 185 (66%) on convincing non-experimental evidence. Only 23% of interventions were category 3.
Conclusions—In common with other medical specialties, the majority of paediatric surgical interventions are based on sound evidence. However, only 11% of interventions are based on RCT data, perhaps reflecting the nature of surgical practice. Further RCTs or research is indicated in a proportion of category 3 interventions.
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Evidence-based medicine aims to ensure that clinical practice is based on the best evidence available. In order to achieve this goal it is necessary to identify areas of current clinical practice where supportive evidence is lacking. For many years a popular if largely unsubstantiated dogma has been that only a small proportion of medical treatment has been proved to be beneficial.[1 2] A recent study by Ellis *et al* has refuted this by demonstrating that 82% of acute inpatient general medicine is evidence-based, either on the basis of randomised clinical trial (RCT) data (53%) or convincing non-experimental evidence (29%).[3] Similar results have been reported in the general practice setting.[4] Whether other specialties can claim such a high proportion is open to question. This study aims to establish the proportion of paediatric surgery that is evidence-based and to identify areas where RCTs, or further research, is required.

Methods

All consecutive paediatric general surgical admissions to Alder Hey Children's Hospital (n=326) during the month of November 1995 were prospectively analysed. The methodology of Ellis *et al*[3] was employed and each patient was allocated a primary diagnosis and primary intervention. Primary diagnosis was defined as the principal diagnosis leading to the patient's admission. Primary intervention was defined as the main intervention (operative or non-operative) performed during admission. Patients admitted for investigation in whom no diagnosis was reached during the study period were excluded (n= 45, 14%). In the department of paediatric surgery there are five consultants and seven registrars. Only one consultant and one registrar were aware of the study during data collection.

Each primary diagnosis/intervention combination was discussed by a paediatric surgical panel consisting of one professor, two consultants, and two paediatric surgical trainees, who classified treatment according to three categories[3] : category 1, treatment based on RCT evidence; category 2, there are no RCT data in support of the treatment modality but there is convincing non-experimental evidence or the validity of the intervention is such that an RCT would be unnecessary or unethical (an example of a self evident intervention is revision of a blocked ventriculoperitoneal shunt in a symptomatic patient); category 3, empirical treatment that was not evidence-based (an example of this is anal stretch in a patient with anal fissure).

Relevant published data were obtained from four sources: the panel's collective knowledge; standard reference works; Plusnet Medline CD-Plus archives (1966–96); ISI Science Citation Index (1984–96) (Bath Information Data Services). Data were stored and analysed on an IBM-compatible personal computer on a Microsoft Access database (Microsoft Corporation, 1994).

Table 1 Category 1 interventions based on RCT data

Primary diagnosis	Primary intervention	No of patients	Reference
Appendicitis	Appendicectomy	12	5
Symptomatic cholelithiasis	Cholecystectomy	1	6, 7
Fistula-in-ano	Laying open and curettage	1	8
Intussusception	Air enema reduction	1	9
Oesophageal stricture	Balloon dilatation	11	10
Oesophageal varices secondary to portal hypertension	Injection sclerotherapy	2	11–16
Pilonidal sinus	Excision of pilonidal sinus and primary wound closure	1	8, 17
Recalcitrant ingrowing toenail	Wedge excision and phenolisation of nail bed	2	19
Total		31	

Results

Of 281 patient interventions in the month of November 1995, 77% were evidence-based, that is category 1 (11%) or category 2 (66%) interventions (tables 1 and 2). Congenital abnormalities requiring surgical correction are listed in table 3. The remaining 23% of interventions were judged to have no evidence

Table 2 Category 2 interventions (self evident interventions or where a RCT would be unethical)

Primary diagnosis	Primary intervention	No of patients
Congenital abnormality requiring surgical correction	Correction of congenital defect	93
Acute non-specific abdominal pain	Admission and observation	25
Acutely tender testicle	Scrotal exploration	7
Pyloric stenosis	Pyloromyotomy	6
Recalcitrant ingrowing toenail	Wedge excision	3
Religious circumcision	Circumcision	4
Suspected blocked ventriculoperitoneal shunt	Admission and observation	4
Blocked/disconnected ventriculoperitoneal shunt	Revision ventriculoperitoneal shunt	3
Central venous access for chemotherapy	Insertion of central venous access device	3
Stable blunt abdominal trauma	Observation	2
Recalcitrant gastro-oesophageal reflux with proved oesophagitis	Nissen's fundoplication	2
Temporary enterostomy	Closure of enterostomy	2
Intussusception secondary to Meckel's diverticulum	Open reduction and diverticulectomy	2
Ovarian torsion with infarction	Oophorectomy	2
Symptomatic non-communicating hydrocephalus	Insertion of ventriculoperitoneal shunt	2
Acute gastric distension with inability to pass nasogastric tube	Laparotomy and insertion of gastrostomy tube	1
Appendix mass	Non-operative	1
Bleeding cervical polyp	Excision of cervical polyp	1
Faecal incontinence (spina bifida)	Antegrade continent enema procedure	1
Displaced gastrostomy tube	Replacement of gastrostomy tube	1
Minor head injury, ventriculoperitoneal shunt in situ	Admission and observation	1
Acute neck abscess	Exploration	1
Ileo-ileocolic intussusception, failed enema	Open reduction	1
Lacerated foreskin with persistent bleeding	Suture of laceration	1
Cervical lymphadenopathy, ? neoplastic	Excision biopsy	1
Complex bleeding oesophagopleural fistula after fistula repair	Oesophagectomy	1
Cervical carcinoma	Hysterectomy and partial vaginectomy	1
Multiple soft tissue injuries after road traffic accident	Debridement and suturing of lacerations	1
Perforated necrotising enterocolitis	Ileal resection and ileostomies	1
Paraphimosis	Reduction of paraphimosis	1
Pelvic abscess after appendicitis	Per rectal aspiration	1
Persistent hypoglycaemia of newborn	Partial pancreatectomy	1
Anorectal polyps	Diathermy excision	1
Rectal polyp	Endoscopic excision	1
Unsightly skin naevus	Excision	1
Sebaceous cyst	Excision of sebaceous cyst	1
Inclusion cyst in operative scar	Excision	1
Bronchial stenosis	Balloon dilatation	1
Phimosis (balanitis xerotica obliterans)	Circumcision	2
Total		185

basis (table 4). Several cases require further explanation. The patient with acute gastric distension (table 2) had adhesive obstruction, and previous fundoplication made passage of an endoscope or nasogastric tube impossible. Surgery for recalcitrant ingrowing toenails appears as both a category 1 and 2 intervention—there is an RCT in support of phenolisation in addition to wedge excision,[19] (category 1), but in some patients phenolisation was not used (category 2). 'Acute non-specific abdominal pain', 'chronic constipation', 'blunt abdominal trauma', and 'acutely tender testicle' have been included as diagnoses. It is recognised that these terms embrace a number of diseases of differing aetiologies; however, in practical terms these are useful categories within which interventional strategies are uniform. For example, when children present with an acutely tender testicle it should be assumed to be due to testicular torsion until proved otherwise.[20] No diagnostic tool has been shown to be infallible[21 22] and therefore surgical intervention in these cases is self evident.

Discussion

The majority of paediatric surgical interventions in our regional paediatric surgical unit are evidence-based and this is in broad agreement with findings from other medical specialties.[3 4] However, the proportion of category 1 (RCT data) interventions was substantially lower than in the case of inpatient general medicine or general practice (fig 1). The relative lack of RCT data supporting paediatric surgical interventions probably reflects the different nature of surgical as against medical practice. By their very nature, many surgical interventions can be classified as 'self evident', for example, correction of life threatening congenital malformations. In addition, much paediatric surgical pathology is rare, with individual centres seeing relatively small numbers of certain conditions. This creates difficulty in RCT design and execution.

Analysis of the 23% of interventions lacking supportive evidence allows them to be subclassified into two further groups: (1) heterogeneous ill defined conditions such as chronic constipation in which the primary pathology is not well understood and is almost certainly multifactorial; treatment is thus empirical and RCT data are lacking; (2) conditions such as bleeding granulation tissue or anal fissure, where subjective clinical experience suggests that patients benefit from the intervention employed.

We recognise that the current study design has limitations. Although several search protocols were employed, it is likely that all relevant literature has not been identified.[23] This would lead to an underestimate of the number of interventions that are based on sound evidence. The two investigators who were aware of the study during data collection were responsible for making diagnoses/ordering interventions and it could be argued that this could have altered clinical practice. However, if

Table 3 Category 3 interventions (interventions with no self evident basis or supportive RCT data)

Primary diagnosis	Primary intervention	No of patients
Chronic constipation	Enemas, manual evacuation under *anaesthesia* with rectal biopsy	28
Uncomplicated head injury	Admission and observation	15
Anal fissure	Anal stretch	9
Recurrent balanitis	Circumcision	3
Phimosis (no histology)	Circumcision	3
Rectal prolapse	Saline injection	1
Rectal prolapse	Rectopexy	1
Tongue tie	Division of tongue tie	2
Ascending cholangitis secondary to biliary atresia	Intravenous antibiotics and fluids	1
Bleeding granulation tissue at gastrostomy site	Topical silver nitrate	1
Varicocele	Embolisation	1
Total		65

Table 4 Category 2 interventions (congenital malformations requiring surgical correction)

| Primary diagnosis (age range in years)	Primary intervention	No of patients
Inguinal hernia	Inguinal herniotomy	33
Undescended testis (2.5–13)	Orchidopexy	21
Hydrocele (2.5–9)	Ligation of patent processus vaginalis	9
Epigastric hernia (3–8)	Epigastric hernia repair	7
Umbilical hernia (2–12)	Umbilical hernia repair	7
Anorectal malformation	Pull-through/anoplasty/postoperative anal dilatation	5
External angular dermoid	Excision	3
Tracheo-oesophageal fistula and oesophageal atresia	Ligation of oesophageal fistula and oesophageal anastomosis	2
Hirschsprung's disease	Pull-through procedure	1
Gastroschisis	Reduction and closure	1
Femoral hernia	Femoral hernia repair	1
Patent vitellointestinal duct	Ligation/excision	1
Thyroglossal cyst	Excision	1
Dermoid cyst	Excision	1
Total		93
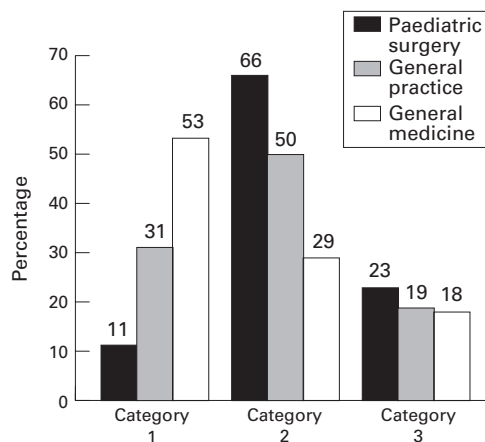
Figure 1   Percentage category of intervention between paediatric surgery, general practice,[4] and inpatient general medicine.[3]

this were true it would only affect a small proportion of cases.

The reductionist approach necessarily adopted for both diagnosis and intervention belies the complexity of this particular group of patients. Patients often suffer from a number of disorders in addition to the primary diagnosis. For example, duodenal atresia may be associated with Down's syndrome and a cardiac defect. Clinical practice is also influenced by less tangible but equally important psychological and social factors, thus, for an antegrade continent enema procedure to be successful,

patients need to be well motivated and have specialised nursing support.[24] Categorising interventions as 1, 2, and 3 should not be equated with ranking in terms of clinical value, for example closure of tracheo-oesophageal fistula is a life saving but category 2 intervention.

The limitations of RCTs, particularly within a surgical context, are well recognised[25]; furthermore, RCT findings are open to various interpretations. The RCT quoted in support of appendicectomy for acute appendicitis concluded that outcome from conservative treatment was similar to that for operative management.[5] However, it was the consensus opinion of the panel that the high rates of recurrent appendicitis coupled with unknown long term outcomes in terms of episodes of adhesive obstruction and female infertility did not justify this conclusion. Finally, some trial data cited here involve adult patients and the relevance of such findings to paediatric practice cannot be assumed.

This study has added weight to the argument that most current medical practice is 'evidence-based'. As in all areas of medical practice, difficulties may be encountered in the application of RCT and other evidence to individual patients. Thus the results of interventions performed in large centres by enthusiasts with wide support may not be achievable in other centres.[26] Evidence-based medicine is only a tool in the surgical decision making process.[27] This review has highlighted areas warranting further examination such as interventions for chronic constipation and the management of anal fissure. The findings from this study are to be incorporated into development of evidence-based critical care pathways where appropriate.

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