



Best Practice Guideline article

## The evidence base for neonatal surgery

Nigel J. Hall, Simon Eaton, Agostino Pierro\*

Department of Paediatric Surgery, UCL Institute of Child Health, London UK

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### ABSTRACT

The practise of evidence based medicine means integrating the clinical expertise with the best available external clinical evidence from systematic research. There is a lack of supporting scientific evidence from rigorous trials in neonatal surgery. The indications for surgery and the type of operation performed in neonates are rarely supported by randomised controlled trials. As a consequence, the majority of the operations performed in neonates are supported by retrospective studies and surgeon preference. This review article is focussed on operations in neonates which are performed by general paediatric surgeons. Only a few randomised controlled trials have been performed in neonatal diseases such as congenital diaphragmatic hernia, necrotizing enterocolitis, pyloric stenosis and inguinal hernia. All of these trials have been based on collaboration between paediatric surgical units highlighting the importance of creating a network of centres that will promote multicentre prospective studies.

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### 1. Introduction

Surgical intervention has, quite rightly, a well-established role in the management of a number of neonatal conditions both congenital and acquired. Surgical approaches have been developed over a period of time from the initial endeavours of pioneering neonatal surgeons to the procedures commonly in everyday use today. Such development has been predominantly a result of necessity, learning from past experience and translation of techniques in use in other surgical fields into neonatal surgery. As neonatal surgical experience has grown, surgeons have begun to develop alternatives to what were once thought to be traditional techniques such that for a number of conditions we now have the luxury of choice in the treatment of these often fragile infants. With choice, there comes a dilemma. Which approach should be used? How should we make the decision?

We now live firmly in the era of evidence based medicine and are required to draw on evidence to guide us in our decisions and justify them. However, when compared with adult general surgeons, who may perform many hundreds of similar operations, general paediatric surgeons perform a great variety of different operations, but each of them may have relatively small numbers. This has the consequence that the evidence base for many paediatric and neonatal surgical procedures is lacking compared with comparable procedures in adults. This was highlighted by Baraldini et al., who performed a study to determine the type of research evidence supporting operations in a tertiary referral paediatric surgical unit [1]. All patients admitted over a 4-week period to two surgical teams were enrolled in

the study and all major operations carried out on each patient were evaluated. Twenty-six percent of the operations were supported by a randomised controlled trial (RCT) (level 1 evidence), but the vast majority of these trials were conducted on adult patients. At that time, the only operation supported by an RCT *in children* was repair of congenital diaphragmatic hernia. The majority of the operations (68%) were based on evidence from published non-randomised prospective or retrospective studies. This study showed that more RCTs were needed in paediatric surgery. Since this study was performed, several RCTs have been performed for paediatric surgical conditions.

It is the aim of this review to examine the current evidence for neonatal surgical procedures. We focus on those conditions of the term and pre-term neonates which would be managed by the general paediatric and neonatal surgeon, excluding conditions affecting the cardiovascular, genitourinary and nervous systems. The evidence that we present will be primarily of level 1. There are many retrospective reviews and case series amongst the literature which may give some guidance as to which approach to a given condition may be superior. By their very nature, these have internal flaws and are subject to bias. We are firmly of the view that the correct way to determine the best approach to a condition where a choice exists is by means of a RCT. This paper is therefore primarily a review of RCT as they relate to neonatal surgery and we include non-randomised studies only where no RCTs exist and the alternative evidence is of sufficient quality or interest to justify its inclusion. The evidence relating to the more common surgical conditions of the neonatal period is presented.

#### 1.1. Oesophageal atresia

Following the first classic description of oesophageal atresia with tracheo-oesophageal fistula by Gibson in 1697, it was not until the

\* Corresponding author. Department of Surgery, UCL Institute of Child Health, 30 Guildford Street, London, WC1N 1EH, UK. Tel.: +44 20 7905 2641.

E-mail address: [pierro.sec@ich.ucl.ac.uk](mailto:pierro.sec@ich.ucl.ac.uk) (A. Pierro).

early 20th century that the first attempts at repair of this congenital anomaly were made. Initially mortality remained high but during the course of the 20th century oesophageal atresia evolved from a condition incompatible with life to having a survival rate in excess of 90% [2]. The principles of surgical management of this condition are the separation of the oesophagus from the trachea where a connection exists by ligation and division of the tracheo-oesophageal fistula and restoration of the continuity of the oesophagus from mouth to stomach. When possible this is undertaken in a single operative procedure. However, the presence of life threatening gastric dilatation in an unstable infant may necessitate emergency ligation of the fistula alone pending repair of the oesophageal atresia once systemic stability has been achieved. Infants in whom the interruption of the oesophagus between upper and lower pouches is too great to permit a primary anastomosis (“long-gap”) may be managed in a staged manner using techniques including delayed primary repair with gastrostomy, cervical oesophagostomy, oesophageal replacement, and continuous extracorporeal tension of the oesophageal ends to encourage longitudinal growth (Foker technique [3]). Despite the lack of quality evidence, it is interesting that the United Kingdom National Institute of Clinical Excellence (NICE) has reviewed the evidence relating to the Foker technique and approved its use despite the evidence considered relating to only 9 infants who underwent this procedure [4]. Whilst the Foker technique may have a role in the management of selected infants with oesophageal atresia, we feel that this technique should be used cautiously and due consideration given to alternative approaches. Recently, thoracoscopic repair of oesophageal atresia has been performed, reportedly with good results [5,6]. However, RCTs comparing thoracotomy with thoracoscopy have not yet been carried out.

Post-operatively the main challenges faced by infants, parents and clinicians are anastomotic leakage, the development of anastomotic strictures requiring dilatation, gastro-oesophageal reflux, oesophageal dysmotility and tracheomalacia. Various techniques have been proposed to minimise the incidence of these post-operative complications. Elective paralysis and ventilation [7] has been proposed as an effective method of minimising anastomotic leakage following ‘tight’ oesophageal anastomosis. Both elective oesophageal dilatation and the routine use of anti-reflux medications have been proposed to reduce the incidence of anastomotic strictures. None of these methods of treatment has been subjected to the rigorous scientific interrogation of a RCT.

### 1.2. Congenital diaphragmatic hernia

Congenital diaphragmatic hernia (CDH) remains one of the most interesting and challenging congenital anomalies of the newborn. Once a condition of extremely poor prognosis, overall survival rates are now in the range of 40–70% with some centres reporting mortality of less than 20%. Central to our understanding of this condition has been the recognition that early surgical repair is not crucial for survival but that delayed surgical approach following improvement in cardio-respiratory function is preferable. Despite this, survival rates are still far from desirable. This has prompted the pursuit of alternative strategies including extracorporeal membrane oxygenation (ECMO) and foetal intervention.

Prenatal diagnosis of CDH has permitted the identification of those foetuses with characteristics suggestive of poor prognosis and high postnatal mortality. A number of prenatal interventions have been suggested in attempts to improve outcome. Whilst technically feasible, prenatal repair of CDH by means of open foetal surgery failed to improve outcome and resulted an increased incidence of premature birth with no survival benefit. Foetal endoluminal tracheal occlusion (FETO) has been investigated as a means of promoting prenatal lung growth in the anticipation that this would improve survival. Following *in utero* FETO in experimental models of CDH,

investigators found an increase in lung growth, improvement in lung compliance and improved postnatal oxygenation and ventilation. Initial reports [8–11] in the human suggested great promise using this technique but a recent RCT investigating FETO in what were considered to be high risk infants with CDH (lung to head ratio < 1.4) was stopped before completion due to a higher than anticipated survival in the control (untreated) group [12]. This resulted in the study being underpowered to demonstrate any benefit in the treatment group. Another RCT investigating the effect of FETO, in infants deemed to be at particularly poor prognosis (liver herniation and lung to head ratio < 1.0), is currently ongoing [13].

Post-natally, a number of ventilatory techniques have been investigated in attempts to improve outcome from CDH. Studies (some RCT) have been performed investigating the effect of inhaled nitric oxide (NO) [14], routine ECMO [15], surfactant usage [16] and partial liquid ventilation [17] in CDH infants. At present there is no evidence of improved outcome in infants with CDH following any of these interventions.

The technique of surgical repair of the diaphragmatic defect is of far lesser importance than management of the infant's cardio-respiratory compromise secondary to pulmonary hypoplasia and associated pulmonary hypertension. Surgical repair of the defect can proceed once the infant's cardio-respiratory status has stabilised. Following the return of the abdominal contents from the thorax to the abdomen, the defect is repaired primarily when possible but using a patch when the defect is too large for primary repair. Retrospective evidence suggests that a biological patch may confer a lower recurrence rate when compared with a synthetic alternative [18]. Surgical repair is possible through a traditional laparotomy incision or via minimal access techniques through both the abdomen and thorax. There is no evidence of improved outcome following minimal access repair when compared with conventional open surgical approach.

### 1.3. Atresia of the mid and hind gut

The surgical principle behind operative repair of duodenal, jejuno-ileal and colonic atresias is restoration of continuity from mouth to anus whilst maintaining as much intestinal length as possible. In the majority of cases a primary repair of the defect is possible. A laparoscopic approach to repair of duodenal atresia has been reported [19] but there is no evidence in favour of either approach. The most significant long-term adverse outcome following intestinal atresia is that of short bowel syndrome in a small group of infants. The underlying aetiology of this is usually the anatomical nature of the underlying anomaly rather than the technique of surgical repair. The high (>90%) survival rates and acceptable long-term gastrointestinal function in the majority of infants provide the evidence in support of current techniques [20]. Controversy does exist, however, in post-operative feeding strategies; some surgeons advocate parenteral feeding for some types of atresia whereas others do not. There is no evidence base either for or against parenteral nutrition.

### 1.4. Anorectal malformations

The management of anorectal malformations remains a challenge for paediatric surgeons mainly due to the high incidence of functional long-term impairment including faecal incontinence, urinary incontinence, sexual dysfunction and fertility problems. The introduction and widespread use of the posterior sagittal anorectoplasty (PSARP) has without doubt improved functional outcome from this complex group of anomalies. However, gathering reliable evidence to support this statement is difficult due to the diversity of anomalies, the functional (and therefore often subjective) nature of the outcomes of interest and indeed the widespread usage of the PSARP procedure thereby precluding meaningful comparison with alternative surgical approaches.

### 1.5. Anterior abdominal wall defects

The anterior abdominal wall defects (gastroschisis and exomphalos) are often considered together due to their anatomical similarities and similarities in their management. The principles of surgery relating to these conditions are to protect the bowel and other eviscerated organs and to achieve their return to the abdominal cavity as soon as possible so that the defect in the abdominal wall can be closed. Infants with exomphalos (eviscerated abdominal contents covered with a sac of amnion) are typically managed operatively with either primary closure in cases of exomphalos minor or with a staged approach (see below) followed by surgical closure in cases of exomphalos major.

Some infants with gastroschisis (eviscerated contents not covered with a sac) are also amenable to primary closure which may be undertaken soon after birth but in others a staged approach may be necessary. In infants in whom primary closure is possible many centres perform this under general anaesthetic but the need for this has been questioned and the concept of primary reduction without anaesthesia at the bedside has been reported [21]. However there is a lack of quality evidence in support of one approach over the other. A Cochrane review failed to identify any RCT addressing this issue and recommended that they be undertaken [22]. None has been.

When a staged approach is required this involves the use of a protective bag known as a 'silo' into which the eviscerated abdominal contents are placed. The silo serves to protect the bowel from the outside environment particularly preventing the bowel from dehydration. It also facilitates reduction of its contents into the abdominal cavity by containing it in such a way that gravity and external pressure can be applied to enhance reduction. Traditionally silos were attached to the abdominal wall musculature surgically but recently the 'preformed silo' product has become available that can be tucked under the musculature and held in place without the need for general anaesthesia or surgical attachment. Following return of the abdominal contents to the abdomen, the abdominal wall defect is closed. This has traditionally been a surgical closure under general anaesthetic but a number of centres are now performing this at the bedside without the need for anaesthesia and achieving excellent cosmetic results.

The advent of the preformed silo has led clinicians to consider whether such a technique should be used for all cases of gastroschisis and that attempted primary closure should be avoided altogether. The potential complications of primary closure include a sudden rise in intra-abdominal pressure which may result in respiratory compromise, organ failure and significant complications. Pastor et al. [23] have recently performed a RCT comparing routine placement of a preformed silo without anaesthetic at the bedside with attempted primary closure either under general anaesthetic or at the bedside. In the group randomised to undergo attempted primary closure, a preformed silo was placed if primary closure was not possible either due to a large discrepancy between volume of eviscerated contents and abdominal capacity or due to an unacceptable increase in intra-abdominal pressure. Unfortunately their study was stopped early due to poor recruitment and analyses demonstrated no difference between the groups in outcome measures of number of days on a ventilator, duration of PN dependency, length of hospital stay, incidence of sepsis and NEC and intra-abdominal pressure at the time of closure. However due to the smaller than anticipated numbers in this study, the trial was significantly underpowered to detect any difference in this outcome measures between the groups. Previous retrospective studies have demonstrated improved outcomes following routine use of preformed silos although there are significant biases in patient allocation attributable to the retrospective nature of these reports [24,25].

One of the most challenging aspects of the treatment of the infant with gastroschisis is the management of intestinal dysfunction following return of the bowel to the abdomen and abdominal wall closure. The precise aetiology of this dysfunction is unclear but it is proposed that there is a degree of intestinal damage sustained *in*

*utero*. A number of interventions have been proposed to improve the intestinal dysfunction including prenatal amniotic fluid exchange, elective pre-term delivery [26,27], elective Caesarian section delivery, early onset of enteral feeds [28] and administration of pro-kinetic agents [29]. The efficacy of some of these has been investigated in the setting of a RCT yet none has been shown to be effective.

Logghe et al. performed a RCT comparing elective delivery at 36 weeks gestation with spontaneous onset of labour [26]. They found no clear benefit in infants who were electively delivered at 36 weeks although the sample size was small.

Curry et al. investigated the effect of enteral erythromycin as a pro-kinetic agent on time taken to achieve full enteral feeds compared with placebo in a prospective randomised study comprising 62 infants with gastroschisis [29]. No benefit was observed in time taken to achieve full enteral feeds nor episodes of sepsis, duration of PN requirement or total hospital stay in infants receiving erythromycin.

### 1.6. Congenital lung lesions

Congenital cystic adenomatous malformation (CCAM) and bronchopulmonary sequestration are congenital lung lesions often detected on routine antenatal scanning. Whilst there is little debate that symptomatic CCAMs should be surgically excised to allow symptomatic relief, controversy exists surrounding the optimal management of asymptomatic lesions. Justification for surgical excision of asymptomatic lesions is the avoidance of symptoms or other complications (e.g. malignant transformation) in the future. Whilst there are no randomised studies comparing surgical excision with non-operative observation, Stanton et al. have recently performed a meta-analysis of the postnatal management of antenatally diagnosed lung lesions [30]. They conclude that the risk of an asymptomatic lesion becoming symptomatic is extremely low and that a non-operative approach may be appropriate for small lesions. Further studies are required to provide reliable data on the incidence of malignant change in congenital lung lesions in order that the risk of this likely rare but significant complication can be balanced against the risks of surgical excision.

### 1.7. Hirschsprung disease

Hirschsprung disease, characterised by an absence of ganglion cells in the nerve plexi of the large bowel most commonly present in the neonatal period with failure of passage of meconium within the first 48 h of birth is often associated with abdominal distension with or without vomiting. Diagnosis is based on a biopsy of the rectum and following this definitive surgery is planned to excise the affected colonic segment. There are a number of operative techniques, the main differences between them being the nature of the anastomosis between the 'pulled through' section of normal bowel, proximal to the excised aganglionic segment and the rectum. Evaluating and comparing these procedures is problematic for many reasons. Firstly, the main outcome measures of interest are long term and primarily relate to bowel function. As is the case following surgical correction of anorectal malformations there are difficulties in quantifying bowel function in such a way that meaningful results can be achieved. In addition there is inter-patient variability in the severity of disease, length of affected intestine and susceptibility to enterocolitis, a well-established complication of Hirschsprung disease. Thus strong evidence in support of one operative technique over the others is lacking.

Despite this, significant advances in the management of neonates with Hirschsprung disease have been made in recent times. With the advent of laparoscopic surgery, many surgeons are performing a pull-through procedure either with the assistance of the laparoscope [31] or in a completely minimally invasive fashion [32]. Early experience suggests that the traditional benefits of minimally invasive surgery

can be achieved with functional outcome similar to that reported following open surgery. However, long-term follow-up of these children is, at present, lacking.

The other recent advance is the use of the primary pull-through procedure in selected infants. The traditional approach to the infant with Hirschsprung disease has been to achieve intestinal decompression with a stoma, to perform a pull-through procedure with this covering stoma and then to close the stoma following successful healing of the pull-through. However it is now clear that selected infants can be successfully managed with a primary pull-through procedure with intestinal decompression achieved pre-operatively with rectal washouts and avoiding the need for a stoma altogether. One potential disadvantage of this is a higher incidence of post-operative enterocolitis [33] but this is not a consistent finding across series [34] and it is evident that the primary pull-through is here to stay.

### 1.8. Inguinal hernia

Inguinal herniotomy is the procedure of choice for neonates with an inguinal hernia (IH). Gross et al.'s report in 1953 of 3874 children who underwent inguinal herniotomy reported a recurrence rate of just 0.15% [35]. The standard approach to inguinal herniotomy was by an open groin incision but laparoscopic repair is now routinely practised with comparable outcomes [36]. In the neonatal population there are a number of issues which remain largely unanswered. These are how the contralateral groin should be managed, whether laparoscopic repair confers any benefit over open repair in this age group and whether repair should be undertaken on an urgent or even emergent basis due to the perceived higher risk of incarceration in the neonatal population.

Management of the contralateral groin in infants with IH remains controversial despite being debated for over 50 years. It is recognised that a proportion of infants with IH will develop a metachronous contralateral hernia but identification of such infants has proved difficult. Some surgeons advocate routine contralateral open groin exploration at the time of repair of IH but this places the contralateral vas deferens and testicular vessels at potentially unnecessary risk. A recent systematic review calculated that the incidence of metachronous contralateral hernia in infants <6 months of age was 11% and that 9 contralateral groins would need to be routinely explored to prevent one metachronous contralateral hernia [37].

The introduction of laparoscopic IH repair has serendipitously provided a unique insight into this problem. Laparoscopy enables the surgeon to visualise both deep inguinal rings at the time of inguinal hernia repair and perform bilateral closure should the contralateral deep ring be open. Fundamental to role of laparoscopic repair of IH repair in neonates must remain the efficacy of the procedure. Initial reports of laparoscopic repair of IH in children suggested a higher recurrence rate than could be achieved with open surgery. Recent RCTs comparing open and laparoscopic IH repair in children have reported similar recurrence rates with both techniques although none has specifically included neonates [38–40]. The role of laparoscopy in treatment of IH and prevention of metachronous IH in infants (<1 year) is currently being investigated in a prospective randomised study ([www.marchtrial.org](http://www.marchtrial.org)).

The optimal timing of IH repair in neonates is unclear. The risk of incarceration of IH is believed to be higher in infants and in particular infants born pre-term when compared with older children [41]. This has led to some surgeons repairing inguinal hernias on an urgent basis in infants and for pre-term infants with an IH to have a hernia repair prior to discharge home. The precise risk of incarceration, however, is unknown as there are no observational studies where children known to have a hernia have been observed without planned elective surgery.

One important consideration in hernia repair in boys is future fertility, because of the possibility of damage to the vas or vessels, either during repair, or if a hernia becomes incarcerated. Very little is known about testicular size and fertility following herniotomy, but hopefully infants who have been recruited to RCTs will provide cohorts who will be followed up into puberty to answer this important question. This also illustrates another problem for top-level evidence in neonatal surgery, that important outcomes may not be apparent for many years. This provides problems, particularly where populations are relatively mobile, as in the UK.

### 1.9. Necrotising enterocolitis

The general principles of surgery for the infant with advanced necrotising enterocolitis (NEC) are to control intra-abdominal sepsis and remove ischaemic or irreversibly diseased intestine whilst preserving as much intestinal length as possible. A number of techniques have been proposed to achieve these aims including resection of bowel with primary anastomosis, resection with stoma formation and the 'clip and drop' technique with subsequent second look laparotomy [42–44]. None of these techniques has been subjected to a RCT to determine superiority over the others and they are all in common usage today with justification for their use coming from a number of series all reporting, in general terms, similar outcomes.

In addition to laparotomy, peritoneal drainage has been proposed as a useful intervention in the infant with perforated NEC. Initially described by Ein et al. [45] as a procedure for infants thought too unwell to tolerate laparotomy, it has subsequently been described as a stabilising manoeuvre [46,47] in the smallest and sickest infants and even proposed as primary definitive treatment [48–50]. Recently, 2 RCTs have addressed the issue of whether primary peritoneal drainage or laparotomy is superior in the smallest infants with NEC. These are summarised in Table 1.

Post-operative treatment of infants who have had surgery for NEC is also open to debate. The period of antibiotic usage, time to introduction of enteral feeds, and type of enteral feed are all areas where practise is based on weak evidence. Although there have been no RCTs, a retrospective cohort study suggested that an early re-introduction of enteral feeds is associated with benefit in terms of hospital stay and decreased incidence of central venous catheter-related sepsis, but apparently without increased risk of recurrent NEC [53].

### 1.10. Pyloric stenosis

The standard surgical approach to the infant with pyloric stenosis is the pyloromyotomy. The procedure most commonly performed is the pyloromyotomy based on the technique originally described by

**Table 1**

RCTs comparing laparotomy with primary peritoneal drainage in infants with perforated necrotising enterocolitis.

Study	Included infants	Number	Main outcomes	Authors' conclusion
Moss et al. [51]	<1500 g	PPD 55 Lap 62	No difference in mortality or dependence on PN at 90 days or length of hospital admission	No effect of procedure on outcome
Rees et al. [52]	<1000 g	PPD 35 Lap 34	No difference in survival, ventilator or PN dependence at 1 or 6 months or length of hospital admission. 74% of infants undergoing PPD required delayed laparotomy	Recommend early laparotomy

PPD = primary peritoneal drain; Lap = laparotomy; PN = parenteral nutrition.

**Table 2**  
RCT comparing open and laparoscopic pyloromyotomy in infants with pyloric stenosis.

Study	Detail	Number	Recovery time	Complications	Other significant findings	Authors' conclusion
Greason et al. [59]	LP vs UMB	LP 10 OP 10	LP < OP	Similar	–	Recommend LP
St Peter et al. [60]	LP vs Open*	LP 100 OP 100	Similar	Similar	Less pain and vomiting with LP	Recommend LP
Leclair et al. [61]	LP vs UMB	LP 50 OP 52	Similar	Similar	Less pain with LP	Recommend OP
Hall et al. [62]	LP vs UMB	LP 87 OP 93	LP < OP	Similar	Less analgesia with LP	Recommend LP

Umb = supra-umbilical; LP = laparoscopic pyloromyotomy; OP = open pyloromyotomy; \*Open in this study was either by supra-umbilical or transverse upper abdominal incision; '<' denotes shorter than.

Ramstedt. A number of modifications to this procedure have been introduced over time. Whilst the underlying surgical procedure has remained constant, the approach to the pylorus has been modified in attempts to improve cosmetic outcome, shorten post-operative recovery and reduce post-operative pain. The pyloromyotomy may be performed via an open incision in the right upper quadrant (RUQ), an open supra-umbilical incision or via a laparoscopic approach.

Four RCTs have studied the effect of surgical approach to the pyloromyotomy on post-operative recovery all comparing laparoscopic pyloromyotomy (LP) with open pyloromyotomy (OP). These are summarised in Table 2. Whilst 3 of these studies recommend LP over OP on the basis of shorter post-operative recovery and/or less post-operative pain or vomiting, one study is notable in its recommendation of OP over LP [54]. Although the incidence of complications was similar in both groups in this study, the authors felt that the higher incidence of incomplete pyloromyotomy following LP precluded the use of this approach despite the difference between the groups not reaching statistical significance (LP 3/50 vs OP 0/52;  $p = 0.11$ ).

A recent meta-analysis [55] including the 3 large scale RCTs concluded that post-operative recovery was shorter following LP with a similar incidence in overall complications between the groups. However, there was a trend ( $p = 0.06$ ) towards a higher incidence of incomplete pyloromyotomy following LP when compared with OP. A further meta-analysis, which included prospective cohort studies as well as the RCT reached similar conclusions [56]. The findings of a trend towards an increased rate of incomplete pyloromyotomy in both these meta-analyses highlight another problem in conducting RCT and meta-analyses of RCT in neonatal surgery. Major complications, such as incomplete pyloromyotomy, are rare so that individual RCTs are not powered to detect them. Even when several RCTs are meta-analysed, rare complications are problematic as RCTs without any complications (e.g. the zero rate of incomplete pyloromyotomy in each arm one of the trials [57]) do not contribute to the overall effect sizes in the meta-analysis when odds ratios or relative risks are used [58]. However, one could also argue that although important, such complications are so rare that they do not pose a *clinically significant risk* on an individual patient basis.

In summary, it appears that duration of post-operative recovery and post-operative pain are shorter following a laparoscopic approach to the pyloromyotomy and that LP is a valid technique so long as due care and attention is paid to avoiding incomplete pyloromyotomy.

## 2. Discussion

Despite the well-established and accepted role for surgical intervention in the management of many conditions affecting term and pre-term neonates, this review highlights the fact that a quality evidence base supporting many of these interventions is lacking. Surgical approaches and techniques have largely evolved over time with outcomes being compared to history rather than being formally compared prospectively. There is a clear need for well designed, prospective,

randomised studies in improving the outcomes of infants with surgical conditions as well as advancing our knowledge. Neonatal surgery is a difficult area in which to conduct randomised controlled trials because of the relatively small number of patients, and the perceived difficulty in getting surgeons to participate and parents to consent to randomisation. In addition, some outcomes are difficult to assess or compare.

There is, however, now clear evidence that successful surgical randomised controlled trials can be achieved even in this patient population. Of notice only a few trials have randomised and studied the number of patients required by the power calculation. Due to the relative small number of surgical neonates in each hospital it is necessary to: 1) develop a collaboration amongst paediatric surgery units to foster multicentre RCTs; 2) change the attitude of clinicians, nurses and parents similarly to what is happening in other specialities; 3) appreciate the importance of protocol, equipoise and clinical relevance in the management of surgical neonates.

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