PEDIATRIC SURGERY

Laparoscopic surgery safe and effective for infantile pyloric stenosis

Laparoscopic surgery has been gaining popularity among pediatric surgeons over the past decade, but its safety and efficacy have not been fully determined. Furthermore, it has only become possible to perform laparoscopic surgery on infants relatively recently, since the development of small-gauge laparoscopic equipment. Infantile hypertrophic pyloric stenosis, one of the most common neonatal conditions, requires surgical intervention. The traditional open surgery technique for the treatment of this condition is still safe and effective with a low risk of complications; however, a new study has confirmed that laparoscopic pyloromyotomy is also safe and effective, and is superior to open surgery in terms of postoperative recovery. This piece of research is "...the first randomized controlled trial in the field of pediatric surgery to demonstrate a significant advantage of laparoscopy over open surgery for any procedure," says lead investigator Nigel Hall.

Dr Hall, from Great Ormond Street Hospital, London, UK, previously reviewed the available evidence on laparoscopic versus open surgery for infantile pyloric stenosis. Evidence suggested that potential benefits of the laparoscopic

procedure existed; however, his analysis also raised some safety concerns. An increased frequency of complications, such as incomplete pyloromyotomy and mucosal perforation, associated with the laparoscopic approach warranted further investigation. The reported conflicting evidence and a lack of good-quality, prospective data from large-scale, randomized studies led Hall and colleagues to perform their international, double-blind, multicenter, randomized, controlled trial. "At Great Ormond Street Hospital we had learnt the technique of laparoscopic pyloromyotomy and were keen to determine if this approach really offered any advantage over the traditional ... procedure," explains Hall. The study was conducted with a team of investigators from six centers worldwide, and was co-ordinated by the Institute of Child Health, London, UK. The study design is the "gold standard" for comparing types of treatment and ... provides the most robust evidence possible to evaluate one treatment with another," explains Hall.

The team performed surgery in 180 infants with pyloric stenosis who were randomly allocated to receive either open or laparoscopic pyloromyotomy. Although the trial aimed to recruit 200 infants, the data monitoring and ethics committee felt the findings at interim analysis were so strong that it recommended that the trial be halted before full recruitment because of significant treatment benefit in one group. The primary outcome measures—time to achieve full enteral feed (defined as two consecutive full-volume feeds without substantial

vomiting) and length of postoperative hospital stay—were significantly shorter in the laparoscopic group than in the open group (median 18.5 h [95% CI 12.3–24.0] versus 23.9 h [95% CI 16.0–41.0] and 33.6 h [95% CI 22.9–48.1] versus 43.8 h [95% CI 25.3–55.6], respectively). "The difference of more than 10 h in length of postoperative stay might mean an extra day in hospital after open pyloromyotomy, with logistical and cost implications." An objective measure of overall postoperative recovery was enabled by the joint analysis of the two primary outcome measures, as this accounted for factors that affect postoperative recovery time, such as wound infection, and individual clinician preference. Incidences of vomiting after the procedure and complications both during and after surgery were similar between the two groups. In addition, the laparoscopic approach was associated with a significantly reduced requirement for analgesia and increased parental satisfaction of surgical scars at follow-up compared with the open approach. The frequency of some complications was increased in the laparoscopic group; however, this difference was not significant.

On the basis of these results, "we feel that most surgeons and parents would choose laparoscopy," says Hall. Laparoscopy has advantages over open pyloromyotomy, and "we recommend its use in centers with suitable laparoscopic experience". The team is now investigating whether laparoscopy is beneficial for other surgical procedures in infants. "Having demonstrated a significant difference in outcome following laparoscopic and open pyloromyotomy our unit is now investigating ... the outcome of open and laparoscopic inguinal herniotomy."

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Original article Hall, N. J. *et al.* Recovery after open versus laparoscopic pyloromyotomy for pyloric stenosis: a double-blind multicenter randomised controlled trial. *Lancet* 373, 390–398 (2009).