



## Population-level surgical outcomes for infantile hypertrophic pyloric stenosis ☆☆☆



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### ABSTRACT

**Objectives:** Determine national outcomes for pyloromyotomy; how these are affected by: (i) surgical approach (open/laparoscopic), or (ii) centre type/volume and establish potential benchmarks of quality.

**Methods:** Hospital Episode Statistics data were analysed for admissions 2002–2011. Data presented as median (IQR). **Results:** 9686 infants underwent pyloromyotomy (83% male). Surgery was performed in 22 specialist (SpCen) and 39 nonspecialist centres (NonSpCen). The proportion treated in SpCen increased linearly by 0.4%/year ( $r = 0.76$ ,  $p = 0.01$ ). Annual case volume in SpCen vs. NonSpCen was 40 (24–53) vs. 1 (0–3). Time to surgery was shorter in SpCen (1 day [1, 2] vs. 2 [1–3]), but total stay equal (4 days [3–6]). 137 (1.4%) had complications requiring reoperation (wound problem 0.6%; repeat pyloromyotomy 0.5% and perforation, bleeding or obstruction 0.2%); pooled rates were similar between SpCen and NonSpCen (1.4% vs. 1.6%,  $p = 0.52$ ). Three NonSpCen had >5% reoperations (within 99.8% C.I. as small denominators). There was no relationship between reoperation and centre volume. Laparoscopic pyloromyotomy had increased risk of repeat pyloromyotomy (OR 2.28 [1.14–4.57],  $p = 0.029$ ).

**Conclusions:** Pyloric stenosis surgery shifted from centres local to patients, but outcomes were unaffected by centre type/volume. Modest reported benefits of laparoscopy appear offset by increased reoperations. Quality benchmarks could be set for reoperation <4%.

**Type of study:** Treatment Study.

**Level of evidence:** Level III.

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Infantile hypertrophic pyloric stenosis (PS) is the commonest reason for an infant to undergo major abdominal surgery and has a reported incidence of 2–5/1000 live births [1]. It is commonly treated by Ramstedt's pyloromyotomy: successful surgery results in prompt and lifelong resolution of symptoms [2]. In the last two decades it has largely been performed either using a curved circum-umbilical incision or laparoscopically. [3,4] Despite randomised controlled trials (RCTs) and meta-analyses, the relative merits of the two approaches remain debatable [5–10].

**Abbreviations:** PS, pyloric stenosis; RCT, randomised controlled trial; SpCen, specialist centres; NonSpCen, nonspecialist centres; DGH, district general hospital; HES, Hospital Episode Statistics.

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North American reports indicate improved outcomes when surgery is performed: (i) in specialist units; (ii) by specialist paediatric surgeons; and (iii) in larger volumes [11–13]. Conversely, UK reports claim surgery is safe in District General Hospitals (DGHs) [14–18]. Where children's surgery should be performed has attracted much attention: in 1989, the National Confidential Enquiry into Perioperative Deaths (NCEPOD) concluded that surgeons and anaesthetists should not undertake occasional practice [19]. Amongst other factors, this has led to decreased volumes of surgery in nonspecialist centres (NonSpCen) [20–27]. Tanner reported 70/annum fewer pyloromyotomies in DGHs (1994–2004) [28].

Whether pyloromyotomy fulfils definitions of specialist surgery is questionable: it requires small infant anaesthetic expertise and is sufficiently uncommon to mean NonSpCen treat few cases [29]. With clear volume–outcome relationships in many conditions, should care be concentrated in the hands of specialist surgeons? Conversely, well-trained general surgeons have delivered good outcomes [16–18]. Other modern healthcare service pressures include calls for greater efficiency (e.g. shorter lengths of stay) and delivering seven-day care. Can this be achieved in a NonSpCen when paediatric expertise may be concentrated in the hands of a few? Finally, a drive to ensure high quality surgical care has been witnessed internationally, requiring agreement of robust outcome measures and evidence-based benchmarks.

Overall, it is unclear whether surgical approach (open vs. laparoscopic) or centre type/volume affect outcomes and hence we undertook the following population-level study.

### 1. Aims

We aimed to assess the national epidemiology, service provision and outcomes of PS, determining whether there are differences in outcome between mode of surgery (open vs. laparoscopic) or hospital type and volume. In order to assist drives for quality assurance, we aimed to determine an appropriate benchmark for surgical complications.

### 2. Methods

Hospital Episode Statistics (HES) data were used to analyse all admissions for PS in England for the 10-year period 2002–2011 [30]. Incidence was calculated for England and Wales [31]. Data are presented as median (interquartile range) unless stated. Odds ratios (OR [95% confidence interval]) are used to represent associations between exposure (groups) and outcomes. Categorical data were compared using the Chi-Squared test. Continuous data were compared using an unpaired student t-test or Mann Whitney U (nonparametric). In order to assess trends over time or with surgical volume, a Pearson's correlation coefficient was first calculated to measure linear correlation between the number of years from 2002 and the number of surgical cases or surgical volume and complications. If this was significantly different from zero, a linear regression model was used to describe the trend. Statistical significance was defined as  $p < 0.05$ .

Full methodology available online (See Text, Supplemental Digital Content 1).

### 3. Results

Over the 10-year study period, 9686 infants underwent pyloromyotomy for PS in England. Infants undergoing surgery were more than four times more likely to be male ( $n = 8219, 83\%$ ). Age at surgery was most commonly 29–90 days ( $n = 6563, 67.8\%$ ), followed by 7–28 days ( $n = 2945, 30.4\%$ ). There was no linear correlation between annual incidence in England and Wales and time: the incidence of PS was relatively static at approximately 1.5/1000 live births ( $r = -0.28, p = 0.44$ ) (See Table, Supplemental Digital Content 2).

#### 3.1. Fewer pyloromyotomies are being performed each year in NonSpCen

Surgery was performed in 22 recognised paediatric surgery specialist centres (SpCen) and 39 NonSpCen. Less cases were performed in NonSpCen each year (Table 1) and the proportion of total cases performed in SpCen increased yearly by 0.4% (linear correlation with time [ $r = 0.76, p = 0.01$ ] and regression slope 0.43 [0.12–0.73]).

**Table 1**

Yearly numbers of pyloromyotomies being performed in specialist (SpCen) and nonspecialist (NonSpCen) centres, along with the proportion of cases treated in SpCen.

Year	SpCen	NonSpCen	SpCen Rate (%)
2002	798	96	89
2003	901	93	91
2004	790	78	91
2005	790	59	93
2006	863	67	93
2007	991	68	94
2008	1002	69	94
2009	1007	66	94
2010	947	80	92
2011	869	52	94

When the first 5 years of the study are compared to the second, the proportion of cases performed in SpCen rose from 91% to 94% ( $p = 0.0001$ ).

As a consequence of most surgery taking place in SpCen (often not local to the patient), 6221 (64%) infants were transferred for surgery with a median one (1–2) day NonSpCen stay prior to transfer. Of these 6221 transfers, 41 were to another NonSpCen.

#### 3.2. Individual NonSpCen surgery volumes are very low in the majority

Median annual case volume in SpCen vs. NonSpCen was 40 (24–53) vs. 1 (0–3). The highest volume SpCen performed 85 (73–117) annually, compared to 11 (9–15) in the highest volume NonSpCen. 17/39 NonSpCen (44%) did fewer than 10 cases in 10 years (5 centres performed a single pyloromyotomy in 10 years). 4/39 (11%) NonSpCen performed greater than 5 cases per year.

#### 3.3. Surgery was more likely to occur at a weekend in SpCen

Admissions to place of surgery were distributed fairly evenly across the week, except for Sundays in SpCen when there were fewer (9.0% of weekly admissions) (See Fig. A, Supplemental Digital Content 3). Surgery was performed across the week, but in SpCen there were fewer cases on a Monday (10.6%) and Tuesday (12.0%) (See Fig. B, Supplemental Digital Content 3). In NonSpCen, surgery was again performed less frequently on a Monday (9.6%) and was rarely performed at the weekend. Infants were significantly more likely to have surgery on a Saturday at a SpCen (OR 2.68, 2.00–3.58,  $p < 0.0001$ ) and on a Sunday (OR 4.43, 3.00–6.54,  $p < 0.001$ ).

#### 3.4. There has been an increase in the use of laparoscopic pyloromyotomy

There was a steady increase in the number of pyloromyotomies performed laparoscopically from 2006, with the rate appearing to reach a plateau of around 20% by 2009 (Table 2). Since laparoscopic pyloromyotomy was taking place prior to 2006, it appears that HES coding has not captured the laparoscopic component of the procedure in earlier cases. A significantly greater proportion of cases were treated with laparoscopic pyloromyotomy in SpCen compared with NonSpCen (11% vs. 1%,  $p = 0.000, OR 12.31 [5.83–25.98]$ ).

#### 3.5. Total hospital length of stay was similar between centre types

Time to surgery once in an operative centre was longer in NonSpCen (1 day [1–2] vs. 2 [1–3], SpCen vs. NonSpCen), but postoperative length of stay was similar (2 days [1–3] vs. 2 [2–3], SpCen vs. NonSpCen). Median total length of stay for the entire cohort was 4 days and this did not differ significantly between hospital types (4 days [3–6] vs. 4 [3–6], SpCen vs. NonSpCen). It therefore seems that the increased wait preoperatively in NonSpCen is offset by the far larger number of transfers into

**Table 2**

Number (Lap Cases) and proportion of total cases (Lap Rate) of pyloromyotomies performed laparoscopically each year.

Year	Lap Cases	Lap Rate (%)
2002	0	0
2003	0	0
2004	0	0
2005	0	0
2006	58	6.2
2007	119	11.2
2008	122	11.3
2009	209	19.5
2010	237	23.1
2011	218	23.7

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