**Title:**

Timing of orchidopexy and its relationship to post-operative testicular atrophy: results from the ORCHESTRA study

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**Sources of Funding:** Mark Gorry Foundation

**Category:** Original article

Presented at national meeting of British Association of Paediatric Surgeons 2017 as an oral presentation.

**Abstract**

**Background:** In 2011 a consensus statement from the British Association of Paediatric Urologists recommended lowering age at orchidopexy to under 1 years old. There are concerns that a younger age at operation may increase post-operative testicular atrophy. The ORCHESTRA study aimed to establish current age at orchidopexy in a multicentre, international audit and see if testicular atrophy was affected by age at operation.   
  
**Methods:** The study was performed over a 3 month period in 28 centres in boys undergoing orchidopexy for unilateral, palpable undescended testes. Data collection was performed using a standardized, pre-determined protocol. The primary outcome was post-operative testicular atrophy. Secondary outcomes were wound infections, re-operations and unplanned hospital stays related to anaesthetic events.

**Results:** 417 patients were included of whom only 48 (11.5%) underwent orchidopexy prior to 1 year of age. There was no difference in anaesthetic complications(<1yrs 0/48 (0%) vs >1yrs 6/294 (1.6%)), p=>0.999. Complete follow-up was available in 331(80%) patients. There was no difference in the atrophy rate in those under one (1/37(2.7%)) versus older boys(9/294) (3.1%)), p>0.999. Re-operation rates were 0/37 in < 1yrs vs 7/294(2.7%) in >1yrs, p=>0.999. There were more wound infection in boys < 1yrs (4/37(10.5%)) vs >1 yrs (7/294(2.4%)), p=0.025.   
  
**Conclusion:** Only 11.5% of boys receive surgery before 1 yrs old. There was no increased risk of post-operative testicular atrophy for early surgery although there was a higher rate of wound infection. Further study is required to demonstrate that early orchidopexy is not inferior to orchidopexy carried out over the age of one.

**Introduction**

In September 2011 the British Association of Paediatric Urologists (BAPU) published a consensus statement recommending that orchidopexy should be performed from as young as 3 months of age although 6 to 12 months of age was considered acceptable.(1) This was based on evidence that operating at an earlier age may improve fertility and reduce the long term risk of testicular malignancy.(2–5) It also assumed that undescended testes which have not spontaneously descended by 3 months of age are unlikely to descend by 1 year of age. (6) Since then, several other professional bodies have issued similar guidance supporting early orchidopexy (7,8) and a recent meta-analysis concluded that the ideal age for orchidopexy was 6 to 12 months of age. (9).

There is, however, a lack of evidence to ensure that changes in practice do not have unforeseen negative consequences. Surgery for undescended testes may result in testicular atrophy and it is not known if operating at a younger age may increase the risk of post-operative testicular atrophy.(10) There is also heightened awareness of the possible detrimental effects of general anaesthesia on the developing brain and resulting in a US FDA safety communication about general anaesthetics in children under 3 years of age.(11)

The ORCHESTRA (ORCHidopexy: does Earlier Surgery affect Testicular Atrophy?) study was designed as a multicentre, international audit of current practice of orchidopexy in relation to BAPU guidance and establish current rates of testicular atrophy post orchidopexy.

**Methods**

The study was a multicentre, international trainee-led prospective audit of practice led by the UK based Paediatric Surgical Trainee Research Network (PSTRN). Data were recorded from an inception cohort of boys undergoing orchidopexy for unilateral, palpable undescended testis. Data were collected from each centre over a 3 month period and outcomes recorded for boys with at least 6 months follow-up. Results are reported in accordance with the STROBE guidelines.(12)

**Centre Eligibility**

Any hospital that provided elective general surgery of childhood in the UK was eligible to enter patients. International centres were contacted through trainee links to these countries. In the UK, trainees ensured that there was consultant oversight and agreement within departments to participate and each centre registered the study locally as a clinical audit. International centres followed their local ethial approval procedures. Data collection was completed by surgical trainees.

**Patient Eligibility**

All boys under 16 years of age in whom orchidopexy was performed for unilateral, palpable undescended testis were eligible for inclusion. The testis was considered palpable either during pre-operative clinical examination or during examination under general anaesthesia. Patients who required laparoscopy to determine testicular position were excluded.

Boys who had a known endocrine or genetic condition that could affect testicular growth and boys who had an orchidopexy following ipsilateral inguinal hernia repair were also excluded.

**Study Outcomes**

The audit standard was defined as the proportion of boys who received orchidopexy before 12 months of age as recommended by BAPU and was set at 100%. The age at referral was also collected to see whether delays in timing of orchidopexy were attributable to late referral.

The primary post-operative outcome was the rate of testicular atrophy at least 6 months following orchidopexy. The audit standard was set at less than 5% testicular atrophy based on a recently published large retrospective case series. (10) Testicular atrophy was measured using a comparison to the contralateral, normally descended testis. At the time of orchidopexy the surgeon was asked to note the size of the testis as a proportion of the contralateral testis using one of the following categories: <25%, 25<50%, 50<75%, 75<100%, 100% and >100% volume compared with the contralateral testis. At follow-up, the clinician was again asked to note the testicular size compared with the contralateral testis. Testicular atrophy was defined as a >50% decrease in size to allow for the fact that this was a pragmatic and subjective measurement and that small differences may be due to inter-rater variability and differences in time intervals between assessments.

Secondary outcomes included: the rate of re-operation/ testicular ascent defined as a testis which was palpable at follow-up but no longer in a scrotal position and deemed to require further surgery where the audit standard was set at less than 2%(13); a surgical site infection rate less than 2% where infection was defined as: purulent drainage from the incision or at least two of: pain or tenderness, localised swelling, redness, heat, fever a clinician diagnosis that this represented a surgical site infection, or organisms and pus cells from an aspirate or wound swab (data were collected on whether patients were given antibiotic treatment for presumed wound infection)(14); and an unplanned overnight stay as a result of an adverse anaesthetic event where the standard was also set at less than 2%. (15)

**Data Collection**

Data were collected on each eligible patient using a standardized online electronic proforma. Patients were identified on a weekly basis from planned elective lists. Pre-operative data such as age at referral and operative data were completed by or with the operating surgeon at the end of the list. Follow-up information was collected at the outpatient clinic at least 6 months after orchidopexy.

Patient anonymised data was entered via a secure webpage online database. Each data collector was granted password access and once an individual patient data collection form was completed a study number was allocated. Trainees entering the data then kept a secure record on the hard drive of a hospital network computer linking the study number to a hospital number used for follow-up. The website generated automatic email reminders at the time point when follow-up was planned.

**Study Size Design and Bias**

A local audit was performed at the lead centre (Oxford Children’s Hospital) performing about 100 orchidopexies per year to inform the study design. Of these about 20% were for intra-abdominal or bilateral undescended testes. A 3 month data collection period was chosen as a balance between achieving reasonable numbers from each centre (estimated at 20 per paediatric surgical centre) and a short enough time frame for enthusiasm for the study to be sustained. The plan was to recruit 10 paediatric surgical centres to obtain 200 patients over 3 months. In addition, recognizing that in the UK more than half of all orchidopexies are performed in district general hospitals(16) often by adult general surgeons or urologists with a specialist interest in general surgery of childhood, the study aimed to recruit 20 district hospitals through the national research collaborative of adult surgical trainees to obtain a further 200 patients, based on data from a moderately sized hospital that reported about 35 orchidopexies per year (17).

**Statistical Methods and Analysis**

Planned statistical analysis included comparing post-operative outcomes between patients operated at less than 1 year of age compared with those operated at over 1 year of age, using Fisher’s exact or Chi squared tests for categorical data. Only those patients who had completed at least 6 months follow-up were included in the outcome analysis. No preregistration exists for the study reported in this article.

**Results**

**Participants**

Some 417 patients were included from 28 centres (13 paediatric surgical centres in the UK, 11 general hospitals in the UK, 4 international paediatric centres in Argentina, Austria, Finland and Lithuania)A further 5 DGHs that registered to take part in the audit did not perform any orchidopexies during the data collection period.

Results were available on age at referral for 356 (85%) boys. The median age at referral was 1 year 8 months (range 1 day to 15 yrs 1 month). Of the 356, 117 (33%) were referred before 1 year of age and 92 boys (22%) had previous documentation of intra-scrotal testes by a health professional prior to diagnosis of an undescended testis and referral.

The median age at surgery was 2 years 6 months (range 3 months to 15 years 4 months) although there was a bimodal distribution with a peak between 1 to 2 years of age and a further smaller peak at around 10 years of age. (Figure 1). The median age at surgery for boys who had ‘ascending testes’ was 6 years 1 month and when these boys were excluded the median age of surgery for congenital undescended testis was 2 years.

Only 48 boys out of 417 (11.5%) underwent an orchidopexy prior to 1 year of age. Of the 28 centres, 17 (61%) had patients who were aged less than 12 months at the time of their orchidopexy. All of the overseas centres performed orchidopexies in boys aged less than 12 months, as did 11 of the 13 UK paediatric surgical centres, but only 2 of the 11 general hospitals.

When boys with ascending testes were excluded, the proportion of boys who received surgery prior to 1 year of age was 14.4%.

**Surgical details**

356 (86%) of patients had their surgery in the UK. In the UK, 58 (16%) boys had their surgery in general hospitals and 298 (84%) in paediatric surgical centres.

In UK specialist centres the primary operator was a consultant in 30% of operations whereas in non-specialist centres the primary operator was a consultant 84% of the time. In specialist centres in the UK and overseas, trainees performed 12% and 16% of procedures unsupervised. (Table 1).

25 (6%) boys had an undescended testis that was impalpable until they were anaesthetised. 60% of undescended testes (250/417) were right sided. 376 (90%) of boys underwent surgery via a groin incision and a separate scrotal incision, while 41 (10%) had a single scrotal incision.

As the study was limited to orchidopexies for testes which were palpable under general anaesthesia, 160 (38%) were found within the inguinal canal, 230(56%) in the superficial inguinal pouch below the external ring of the inguinal canal, with 26 (6%) w in an ectopic location (3 perineal, 8 lateral to the scrotum, 4 lateral to the external ring, and 10 described as ectopic but without precise location. (Table 2).

At the time of orchidopexy, nearly 80% of undescended testes were recorded to be at least 75% of the volume of the contralateral testis. Only 9% were less than half the volume of the contralateral testis. In 86(21%) patients the undescended testis was noted to have a dissociated vas.

**Outcome**

**Testicular atrophy**

Follow-up at 6 months post-orchidopexy was available for 331 (80%) patients. Of these, 10 (3.0%) had an atrophic testis (reduction in size compared to operation of more than 50%). There was no significant difference in testicular atrophy between those operated prior to 12 months (1/37 (2.7%)) compared with those operated after 12 months of age (9/294(3.1%))p=>0.999). Among operations performed by a trainee without consultant supervision, only one patient (2.2%) developed testicular atrophy. (Table 3).

**Testicular re-ascent**

Seven (2.1%) testes were noted to have ascended post-operatively. None of the patients with testicular re-ascent had their surgery prior to 12 months of age. A further 12 (3.6%) patients have been booked for further follow-up because their testes were high in the scrotum and there was concern that they may need further surgery. None of the testicular re-ascents were in patients operated via a single trans-scrotal incision.

**Anaesthetic complications**

There were 6 (1.4%) unplanned overnight admissions. In 2 patients apnoeic events occurred in recovery, one patient was slow to wake, two patients required additional pain relief (one had undergone a circumcision under the same GA) and one patient did not pass urine for several hours and also had issues with pain management.

None of the unplanned overnight admissions were in infants under 12 months of age.

**Surgical site infections**

There were more wound infections in younger boys. 4 out of 37 (10.5%) boys operated under 12 months of age developed wound infections compared with 7 out of 294 (2.4%) boys older than 12 months of age at the time of surgery. This was statistically significant (p=0.025).

**Discussion**

This study did not show an increase in testicular atrophy amongst boys operated at less than 12 months of age suggesting that current guidance is not associated with worse early post-operative outcomes. The 3.0% rate of testicular atrophy is less than the preset audit standard of 5% atrophy and similar to that reported in recent observational studies which range from 2.6-5.0%. (10,18,19).

The secondary outcome of testicular re-ascent was similar between those operated at less than 12 months compared with those operated after 12 months. There was a 2.1% rate of re-operation during the 6 month follow-up period which was in line with the audit standard of 2%. While there were no testicular re-ascents in boys operated before 12 months of age, this was not statistically significant reflecting the small numbers in this group. There may be advantages to operating at a younger age because the distance that the testis is moved is less in absolute terms. However, there were a further 12 (3.6%) patients who remained under review due to concerns that the testis was lying high in the scrotum and might need a redo orchidopexy. A weakness of the study was that longer follow-up was not obtained to check that there is not a higher rate of redo surgery than we have reported.

In orchidopexies performed via a single trans-scrotal incision reported rates of testicular re-ascent vary from 0 to 4.5%. (19,20) There were no testicular reascents in boys who underwent orchidopexy via a single trans-scrotal incision in this study supporting its use in selected patients.

Anaesthetic complications were also similar in both groups and there was a low overall rate of unplanned post-operative admissions of 1.4% compared to the audit standard of less than 2%. There were no recorded adverse anaesthetic events in boys operated at under one year of age. However, the APRICOT study which included over 30,000 children undergoing a general anaesthetic found that there was 12 % decreased risk of anaesthetic complication for each additional year of age. (21) A weakness of this study was that no data were collected on intra-operative anaesthetic events.

There was a significantly increased risk of a surgical site infection requiring antibiotics in boys under 12 months of age. In this age group the wounds are more likely to be exposed to urine and faecal contamination from wearing nappies. It may be that the younger boys would benefit from an occlusive dressing or wound glue application.(22)

There are several limitations to this study. It was hoped to include more non-specialist centres in the UK through the adult surgical trainee research networks, but only 16 centres were recruited. A much lower number of orchidopexies were performed in each district hospital than predicted and several registered hospitals performed no orchidopexies during the study period. The majority of orchidopexies were performed in specialist centres and although they showed equivalent outcomes in different age groups it is not clear whether this would be the case outside specialist centres. Only 4 boys were operated under the age of 1 year in non-specialist centres. In the UK this has implications for the design of treatment pathways for undescended testes. Until recently most orchidopexies were performed in non-specialist centres however there has been a trend towards more children receiving surgery in specialist centres and trying to achieve a younger age at orchidopexy may further accelerate this. (16,23,24)

Despite most orchidopexies being performed in specialist centres, this study found that only 11.5% of orchidopexies were performed before 12 months of age and this meant the comparisons of outcomes involved very unequal numbers of patients. The reasons for older age at orchidopexy appeared to be multi-factorial: delayed referral, waiting times and ascending testes. In this cohort, 22% of boys had an undescended testis which had been previously documented as intra-scrotal by a health professional. This is not dissimilar to a multi-centre study in Germany which found that 27% of orchidopexies were performed for ascending testis. (25) In the UK, baby checks are carried out routinely at 6 to 8 weeks’ of age by primary care physicians. The prevalence of cryptorchidism has been reported to fluctuate during the first year of life starting off at 5.9% of newborns, dipping to 2.7% at 3 months before unexpectedly rising again to 6.7% at 1 year of age. (26) Baby checks may well take place when more testes are palpable in the scrotum but a proportion of these do ascend over time. The latest edition of Health for All Children which describes best practice for health screening in primary care emphasizes urgent referral for bilateral undescended testes found at the 6 week check but makes no recommendation for management of unilateral undescended testes. (27) The recent commissioning guide for paediatric orchidopexy published by the Royal College of Surgeons recommended referral at 6 months of age for undescended testes. (28)

Only 80% of the patients had follow-up documented at 6 months following surgery. As the study was registered as a prospective audit of practice, direct contact with study participants outside of the usual standard of care was not permitted. A study that looked at factors associated with non-attendance at follow-up appointment found a similar 80% attendance rate for orchidopexy follow-up visits in the Canadian healthcare system. (29) The loss to follow-up of 20% of patients means that there was systematic bias in the outcome reporting of post-operative testicular atrophy. As the baseline demographics of patients with or without follow-up were similar, it seems likely that that parents would be more inclined to attend for follow-up if they had ongoing concerns, so underestimation of the rate of atrophy seems unlikely. (Supporting information, Table S1).

Testicular volume was assessed clinically by the surgical team responsible for the patient leading to observer bias and interrater variability. The study protocol minimized these risks by requesting that testicular volume was compared to the contralateral testis and that to count as testicular atrophy volume had to reduce by 2 groups (>50% difference) in the classification system. There is a lack of consensus of what constitutes testicular atrophy. Ein et al defined testicular atrophy as a loss of volume of more than a third compared to the contralateral testis, whereas Carson et al deemed more than a 50% loss of volume counted as testicular atrophy. (10,30) Both sets of data were collected retrospectively from chart reviews relying on physician descriptions of the testis and it is unclear how testicular volume was assessed or consistently documented. The ORCHESTRA study had clear definitions of how to assess and classify testicular size. This, alongside, contemporary data collection should have improved the robustness of the data.

The pragmatic design used is reflective of standard clinical practice and therefore the results should be generalisable. There was no restriction on the operating grade of the surgeon or the surgical approach. The results did not show that there were worse outcomes in those patients who had been operated on by trainees and supports unsupervised trainee operating when their trainers consider them to be competent to perform an orchidopexy.

Robust evidence is still needed to influence clinicians to refer boys at an earlier age for consideration of orchidopexy and to satisfy surgeons that there is no increase in risk of early post-operative complications. The present study did not show an increased risk of post-operative testicular atrophy in patients operated at less than 12 months of age suggesting that current guidelines are safe, despite the current low rate of compliance.

**Other Information**

The Mark Gorry Foundation provided £3600 which was used to fund the secure online database. The trustees of the charity were not involved in the study design.

**Acknowledgements**

This study was registered with each participating centre’s audit and research department and the application included the plan for data analysis.

The authors have no declared conflicts of interest.

**Supporting information Table S1 Characteristics of patients with and without follow-up![Table

Description automatically generated]()**

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