

Testicular torsion

Study protocol - June 2022

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Introduction

Testicular torsion occurs when the spermatic cord twists and interruption of the blood supply to the testis occurs. Testicular torsion is a surgical emergency requiring prompt diagnosis and surgical intervention to preserve the testis. Delay in presenting to hospital has been consistently shown to lead to poor outcomes.¹ After admission to hospital for suspected testicular torsion, operative delay also adversely affects the chance of salvaging the testis. In a systematic review of 1,283 patients, when surgical intervention occurred within a six-hour window from the onset of testicular pain, there was a 97% chance of the patient's testis being saved. Whilst the study concluded that survival percentages are significant, beyond the widely accepted time-period of 6-8 hours, the salvage rates decreased, the longer that surgical intervention was delayed.²

The condition affects 3.8 per 100,000 males under 18 years per year and accounts for 10-15% of acute scrotal disease in children, where 42% undergo an orchidectomy.³ There are two peaks in incidence; around puberty which accounts for 65% of all torsions, and in the new-born period. The UK epidemiological data for testicular torsion has not been updated but historical annual incidence was 1 per 4,000.⁴ Data from England and Wales shows in 2020/21 there were 4,573 admissions in patients aged 1-24 years with a diagnosis code of N44 (Torsion of Testis).^{5,6}

At operation, there are two possible procedures: testicular fixation, when the testicle can be saved and fixed to prevent recurrent torsion; and orchidectomy, where the affected testicle is not salvageable and must be removed. In either case it is also standard practice to fix the other testicle. Outcomes vary, depending upon age group. Neonates, typically have non-salvageable testes following testicular torsion. The incidence of testicular torsion in the neonatal period over a 13-year period was calculated as 6.1 per 100,000 live births. In a study of 24 neonates diagnosed with torsion over that 13-year period, none of the testes could be salvaged.⁷ This study will however, focus on the pubertal age group in whom the time of onset of symptoms may be easier to identify, and in whom either a testicular fixation or orchidectomy is performed. This will enable us to interrogate the entire pathway of care.

A range of specialties and health services are involved in the care of patients with testicular torsion, including the NHS 111 service, ambulance, primary care, and secondary care with the potential for delay in diagnosis and treatment occurring at any point of the pathway.

Delay in diagnosis and treatment are the main factors that lead to poor outcomes.⁸ Delays from the onset of symptoms to surgical intervention increase the rate of irreversible ischaemia which can lead to testicular loss, potentially resulting in subfertility or infertility and psychological trauma. In addition, missed testicular torsion will result in testicular atrophy which might result in later surgery and prosthesis.

There may be an initial delay on the part of the adolescent male to seek medical assistance due to a 'watch and wait' approach by them and their parents; a lack of public awareness about the pathology of testicular torsion; and an unwillingness to trouble healthcare services for fear of embarrassment or raising a false alarm.⁸

Once help is sought, delays can occur at the initial points of contact with healthcare services. In 2019 the Healthcare Safety Investigation Branch (HSIB) report reviewed the diagnostic and treatment pathway and identified 'system-wide' delays. The report found that the accuracy, accessibility, and variability of national guidance on the diagnosis and treatment of testicular torsion was leading to delays in treatment. In one notable example, a patient had to undergo an orchidectomy due to delays in referral to emergency care, first by NHS 111 and then by primary care. While the NHS 111 service have upgraded their clinical pathway for patients with acute testicular pain aged 16-25, the report still found that the lack of standardised guidelines for GPs triaging these patients over the phone was leading to delayed diagnosis and treatment.⁹

When patients with suspected testicular torsion present to hospital there are many factors that can contribute to delay in diagnosis and treatment. Commissioning guidelines state that assessment and surgical intervention should be performed locally, and that the transfer of a patient with suspected testicular torsion to a tertiary centre should only occur in exceptional circumstances.¹⁰ Despite this, the GIRFT Paediatric surgery and urology (2021) report found that in some specialist Trusts one in four patients had been transferred from another organisation. The GIRFT report showed that in a few instances this was due to a lack of clear organisational policy on which surgical discipline should perform the scrotal exploration. General surgeons had, therefore, refused to perform the procedure, which meant patients had to be transferred to a specialist centre. The report concluded that scrotal exploration is a relatively simple procedure that can be undertaken by all general and urological surgeons, and that there was no evidence to support the considerable variation in the age at which surgeons and anaesthetists were prepared to treat patients with suspected testicular torsion.¹¹ However, prior to recent changes in the Intercollegiate Surgical Curriculum Programme (ISCP) general surgeons have not been required to gain competency in treating testicular torsion.¹² Without the maintenance of competency in performing a scrotal exploration, many surgeons feel hesitant performing a procedure they do not regularly undertake.

Another possible source of in-hospital delay is the accuracy and use of diagnostic tools. The Testicular Workup for Ischaemia and Suspected Torsion (TWIST) score has been validated by non-urologists as accurate in ruling out testicular torsion in low-risk patients and allowing prompt referral to surgery in high-risk patients without the need for an ultrasound.^{13,14} 2014 the NHS National Reporting and Learning System (NRLS) looked at the use of ultrasound when assessing patients with suspected testicular torsion. A search of all incidents exported to the NRLS dataset between 1st April 2012 and 31st March 2014 generated a total of 289 reports. Ninety-five of these incidents were identified to be associated with delay in treatment for patients with suspected testicular torsion, with twenty-eight classed as a missed diagnosis. A systematic review and meta-analysis conducted in 2018 found that whilst an ultrasound can be useful in predicting testicular loss, it ultimately delays surgical intervention for patients highly suspected of having testicular torsion and contributes to an increase in orchidectomies.²

There can be a great psychological toll on patients with testicular torsion who have undergone an orchidectomy. In 2010, Skoogh et al surveyed 960 testicular cancer survivors across Sweden and Norway and revealed the extent to which males who have undergone an orchidectomy can experience feelings of loss, shame, or uneasiness. Thirty-two percent of respondents reported missing their removed testicle and 26% felt shame or uneasiness following the removal. The proportion of respondents who had a prosthesis fitted reported these feelings at a much lower rate. It concluded that the fitting of a prosthetic implant helps to prevent unwanted feelings of loss, shame and uneasiness following an orchidectomy.¹⁵ Despite evidence that many patients would benefit from a prosthesis, there is no consensus as to when the optimal time is for prosthetic implantation following an orchidectomy;¹⁶ some preferring to perform the operation in children, and others in the pubertal group.¹⁷ The extent to which psychological support is offered following an orchidectomy is also unclear and anecdotally, varies across the UK.

Guidelines and standards

- Sharp et el. 2013. Testicular torsion: Diagnosis, evaluation and management. https://www.aafp.org/afp/2013/1215/afp20131215p835.pdf
- British Association of Paediatric Urologists, British Association of Paediatric Surgeons, Royal College of Surgeons. 2016. Commissioning guide: Management of Paediatric Torsion. <u>https://www.england.nhs.uk/mids-east/wpcontent/uploads/sites/7/2018/03/torsion-commissioning-guide.pdf</u>
- British Association for Sexual Health and HIV. 2019. United Kingdom BASHH national guideline for the management of epididymo-orchitis. <u>https://www.bashhguidelines.org/media/1242/eo-2019.pdf</u>
- Healthcare Safety Investigation Branch. 2019. Management of Acute Onset Testicular Pain. <u>https://hsib-kqcco125-</u> <u>media.s3.amazonaws.com/assets/documents/HSIB_full_report_Management_of_Acute_Onset_Testicular_Pain.pdf</u>
- European Society for Paediatric Urology, European Association of Urology. 2020.
 EAU Guidelines on Paediatric Urology. <u>https://uroweb.org/wp-</u> content/uploads/EAU-ESPU-Guidelines-on-Paediatric-Urology-2020.pdf
- BMJ Best Practice testicular torsion. 2020. <u>https://bestpractice.bmj.com/topics/en-gb/506</u>
- Getting It Right First Time. 2021. Paediatric General Surgery and Urology. GIRFT Programme National Specialty report. <u>https://www.gettingitrightfirsttime.co.uk/surgical-specialty/paediatric-surgery/</u>
- NICE CKS scrotal pain and scrotal swelling <u>https://cks.nice.org.uk/topics/scrotal-pain-swelling/management/testicular-torsion/</u>

Aim and objectives

Overall aim:

To review the complete pathway and quality of care provided to children and young people 2-24 years of age who present to hospital with testicular torsion

Objectives

Organisational

To review:

- Protocols for the management of testicular torsion and scrotal pain suggestive of torsion
- Relevant training for healthcare staff
- Networks of care (including primary care)
- The appropriateness of transfer arrangements
- The availability of staff (including the responsible consultant, appropriately trained and experienced anaesthetic, and other staff)
- The availability of facilities (including diagnostics)
- Emergency surgery access (including access to paediatric and adult services)
- The availability of information for patients and parent carers
- Follow-up services
- Audit

Clinical

To review:

- Patient and parent carer knowledge of torsion prior to the clinical episode
- Pre-hospital care (including the referral process, the role of primary care, urgent care involvement and delay in presentation)
- The admission process (including delays in assessment (including ultrasound) and the transfer of patients)
- The assessment of patients and decision making
- The use of accurate diagnostic tools
- Staffing arrangements (including the grade/specialty/experience of clinicians assessing, diagnosing and treating patients)
- The timeliness of surgery (recognition that suspected testicular torsion is a surgical emergency)
- The decision-making process
- Surgical practice in respect of fixing testes at time of orchidectomy/exploration
- The consent process
- Post-operative complications
- Serious Untoward Incident data to highlight areas of care for improvement
- The follow-up of the patient (including resources available for young people and parent carers, the psychological impact of the admission, the use of prostheses and the long-term sequalae)

Methods

Inclusion criteria

Patients aged 2 to 24 years, inclusive, admitted to hospital with testicular torsion.

Young people will be identified using the following ICD10 and OPCS codes:

ICD10 code

- N44: Torsion of testis
- N45: Orchitis and epididymitis collected to give context but not for inclusion in peer review
- N44.03: Appendage of testis where available, collected to give context but not for inclusion in peer review
- N50.819: Testicular pain where available, collected to give context but not for inclusion in peer review
- N50.82: Scrotal pain where available, collected to give context but not for inclusion in peer review

OPCS codes

- N03.4: Exploration of scrotum
- N05: Bilateral excision of testes (N05.1; N05.2; N05.8; N05.9)
- N06: Other excision of testis (N06.1; N06.2; N06.3; N06.4; N06.8; N06.9)
- N08: Bilateral placement of testes in scrotum (N08.2; N08.3; N08.4; N08.8; N08.9)
- N09: Other placement of testis in scrotum (N09.2; N09.3; N09.4; N09.8: N09.9)
- N13.2: Fixation of testis
- N13.3: Reduction of torsion of testis
- N13.5: Exploration of testis

If at least one of the ICD10 codes are present, the patient should be included on the patient identification spreadsheet. To be included in the peer-review aspect of the study, both one of the included procedure codes and ICD10 code N44 must be present.

Exclusions

ICD10 codes

- Malignancy (ICD10 code C62 (Malignant neoplasm of testis) or C63 (malignant neoplasm of other and unspecified male genital organs) + OPCS codes N08 or N09)
- Patients who undergo orchiopexy for cryptorchidism (OPCS codes N05 or N06 & ICD10 code Q53 (Undescended testicle)
- Testicular rupture/traumatic testicular injury (ICD10 code S30.2; S30.9; S38)

OPCS codes

- N05.3: Bilateral inguinal orchidectomy (Includes: Bilateral inguinal orchidectomy and excision of spermatic cord)
- N06.5: Division of cremaster
- N06.6: Inguinal orchidectomy NEC (Includes: Bilateral inguinal orchidectomy and excision of spermatic cord)
- N07: Extirpation of lesion of testis
- N08.1: Bilateral microvascular transfer of testes to scrotum
- N09.1: Microvascular transfer of testis to scrotum NEC

Other

• Patients admitted to the independent sector

Data sampling timeframe

The timeframe from which data will be sampled will be the 1st April 2021 – 31st March 2022.

Participating providers of healthcare

All acute hospital providers where patients with testicular torsion might be admitted will be asked to participate in the study. Primary care practices will be asked to participate if it is identified that a patient selected for inclusion in the study was admitted to hospital following a referral from primary care.

Incidence and prevalence of the exemplar conditions

Table 1. Nationally collated hospital admission data

Hospital Episodes Statistics (HES) 2020/21; Patient Episode Database for Wales (PEDW) 2020/21; Department of Health (NI)

	HES data 2020/21	PEDW data
	(Age 1-24 years)	2019/20
Diagnosis (ICD 10) code		
Torsion of testis (N44)	4,398	175
Procedure (OPCS) code		
Exploration of scrotum (N034)	1,314	55
Bilateral excision of testes (N05)	8	0
Other excision of testis (N06)	1,421	56
Bilateral placement of testes in scrotum (N08)	1,698	37
Other placement of testis in scrotum (N09)	3,755	145
Fixation of testis (N13.2)	1,565	
Reduction of torsion of testis (N13.3)	368	19
Exploration of testis (N13.5)	447	36

*From PEDW: the presence of an ICD10 code and OPCS code, n=77. This is approximately 44% of admissions with an ICD10 code for testicular torsion. Based on this, this would equate to 1,935 a year in England.

**From pilot data collection: 458 patients with an ICD10 code and OPCS code for testicular torsion were identified from 32 Trusts/Health Boards. This is an average of 14 per Trust/Health Board per year. Based on this, a year's data return from 146 Trusts/Health Boards would identify approximately 2000 patients from which to sample for inclusion in the peer review process

Study promotion

Prior to data collection, NCEPOD will contact all acute hospital and primary care providers. The study will be promoted to young people and parent/carers via patient groups, third sector organisations, NCEPOD Local Reporters (sending the study poster on to the relevant departments), via any study contacts recruited, and via the relevant Colleges and Associations.

Study method test

The data collection methods and data collection tools will be tested to ensure they are robust before the full study is run.

Methods of data collection

There will be five main ways of collecting data for the study:

1. Patient/parent carer views will be collected through focus groups and an on-line anonymous survey. We will work with Local Reporters, and relevant charities (e.g. The Urology Foundation) to encourage involvement.

- 2. Clinician views will be collected through interviews and an on-line anonymous survey. We will work with Local Reporters and study contacts to encourage involvement from clinicians and commissioners.
- 3. An organisational questionnaire will be sent to all acute hospital providers to which patients with testicular torsion or pain leading to testicular torsion might be admitted.
- 4. Clinical data collection: For a sample of patients, a questionnaire will be sent to the surgeon who was responsible for the care of the patient at the time of the operation. A questionnaire will also be sent to the primary care practitioner responsible for the patient at the time referral to hospital (where applicable).
- 5. Case note review: Copies of selected extracts of case notes will be collected for peer review.

Further details on the methods of each method of data collection are given below.

1. Anonymous on-line patient and parent carer survey and focus group interviews

The survey and focus group interviews will gather data on the patient and parent carer views on the care received prior to and during an admission with testicular torsion or pain leading to testicular torsion. The data will not be linked to any other aspects of data collection.

2. Anonymous on-line clinician survey and interviews

The survey and interviews will gather data on clinician views of the services available for them to provide to patients admitted with testicular torsion or testicular pain leading to torsion. The data will not be linked to any other aspects of data collection.

3. Organisational questionnaire

Data collected will include information around the organisation of services, the use of protocols, training, networks of care, transfer arrangements, the availability of staff and facilities, emergency surgery access, information for patients and families and follow-up arrangements. Questionnaires will be sent to all hospitals participating in the study via the online questionnaire system.

4. Clinical data collection

Patient identification

The Local Reporter will be asked to complete the patient identification spreadsheet with the details of all patients admitted to their organisation during the study time period, with the included ICD10 and OPCS codes. The data fields requested will include NHS number, hospital number, date of birth, date of admission, source of admission, primary ICD10 code, all ICD10 codes, all OPCS codes, discharge destination, date of discharge, clinician code and specialty, the primary care practice details and the opt out status of the patient.

Clinician questionnaires

Two questionnaires will be used to collect clinical data for this study:

- 1) Hospital clinician questionnaire
- 2) Primary care clinician questionnaire

Hospital clinician questionnaire

The clinician questionnaires will be sent to the NCEPOD Local Reporter for dissemination via the online questionnaire system. A reminder will be sent at six weeks and ten weeks where

the data is outstanding. Up to 10 patients per hospital will be sampled for inclusion in the study. Sampling will be biased to patients undergoing orchidectomy (N05 & N06).

Primary care clinician questionnaire

The primary care clinician questionnaire will be sent for those patients identified as being referred for the admission by their GP (identified via the completed hospital clinician questionnaire). The questionnaire will be sent directly to the GP for completion either via the online questionnaire system, or as a hard copy questionnaire if the online system cannot be used. A reminder will be sent at six weeks and ten weeks where the data is outstanding.

5. Case note review

The case note review will focus on the group of patients who were admitted to hospital with testicular torsion or testicular pain leading to torsion during the study period, 1^{st} April 2021 – 31^{st} March 2022.

Notes relating to the index admission will include:

- 111 Pathways notes (from Adastra or similar) (where available)
- All primary care notes which could relate to the testicular torsion including GP consultations, out of hours or ED attendances, discharge summaries and follow up letters
- Ambulance Patient Report Form
- Medical and nursing notes from the emergency department clerking to discharge
- Imaging reports
- Operation notes
- Anaesthetic chart
- Consent forms
- Discharge summary
- Follow-up clinic letters

Upon receipt at NCEPOD the case notes will be redacted if not already done so prior to sending.

Reviewer assessment form

A multidisciplinary group of reviewers (detailed below) will be recruited to assess the case notes and questionnaires and provide their opinion on what went well and what did not go well during the process of care via the reviewer assessment form.

Area of enquiry	of enquiry Method of data collection						
Primary care	Clinician questionnaire	Identifiable					
	Online surveys and focus groups/interviews	Anonymous					
Acute hospital care	Case notes, clinician questionnaire, organisational questionnaires	Identifiable					
	Online surveys and focus groups/interviews	Anonymous					

Table 2 summarises the data sources for significant points along the pathway.

Sample Size

Data source	Target number
Young person online survey (non-identifiable)	50
Parent/carer online survey (non-identifiable)	50
Clinician online survey (non-identifiable)	300
Organisational questionnaire	~250

Hospital clinician questionnaires	Up to 10 per hospital
Case note review	Up to 10 per hospital

Analysis and Review of Data

Reviewers

A multidisciplinary group of reviewers will be recruited to assess the case notes and questionnaires and provide their opinion on what went well and what did not go well during the admission. The reviewer group will comprise surgeons (general, urology and paediatric), physicians (general and paediatricians), emergency medicine clinicians, radiologists, nurses, anaesthetists and general practitioners.

An advert will be sent to Local Reporters to disseminate throughout the relevant departments. It will also be placed on the NCEPOD website. Successful applicants will be asked to attend a training day where they will each assess the same two cases to ensure consistent assessment. A number of meeting dates will be arranged, and each reviewer will then be asked to attend a minimum of a further 4 meetings. NCEPOD staff will ensure there is a mix of specialties at each meeting from across the UK. Each meeting will be chaired by an NCEPOD clinical coordinator who will lead discussion around the cases under review. The meetings will either be held in person in the NCEPOD office, or over Microsoft Teams with secure and temporary access to the case notes for review (not downloadable or printable by the case reviewer). Towards the end of the study the reviewers will be invited to attend a meeting where the data will be presented to and discussed with them. The reviewers will also be sent two copies of the draft report for their comment as this is developed.

Confidentiality and data protection

All electronic data are held in password protected files and all paper documents in locked filing cabinets. As soon as possible after receipt of data NCEPOD will encrypt electronic identifiers and anonymise paper documents. Section 251 approval has been obtained to perform this study without the use of patient consent in England and Wales.

Ethical approval will not be required to undertake this study. Duty of candour is covered by the NCEPOD Cause for Concern policy, which ensure that any cases reviewed as less that satisfactory and as a cause for concern are discussed and action taken where required.

Study outputs

On completion of the study a report will be published and widely disseminated to all stakeholders to encourage local quality improvement (QI) (further details available in the communication plan). In addition to the report, supporting tools will be made available including:

- A summary report and summary sheet
- Infographics
- The recommendation checklist
- An audit tool
- A slide set
- A guide for commissioners
- Quality improvement tools
- Useful links for young people and parent carers

Examples of good practice will be shared, and additional QI tools will be developed where appropriate. Key messages from the report will be shared via social media.

Following publication, the report findings will be shared at national and local conferences, study days and other events; and papers submitted to journal for consideration for publication.

Data sharing

Post publication of the study there is the potential to share anonymised data sets with interested parties working in the same field. This will be undertaken following a strict process and will ensure the data does not become identifiable in their nature due to small numbers.



Timescale

	Aug 21	Sept 21	Oct 21	Nov 21	Dec 21	Jan 22	Feb 22	Mar 22	Apr 22	May 22	June 22	July 22	Aug 22	Sept 22	Oct 22	Nov 22	Dec 22	Jan 23	Feb 23	Mar 23	Apr 23	May 23	June 23	July 23	Aug 23	Sept 23	Oct 23	Nov 23	Dec 23	Jan 24	Feb 24	Mar 24
	21	21	21	21	21	2	22	22	22	22	22	22	22	22	22	22	22	3	23	23	23	23	23	23	23	23	23	23	23	4	24	24
Form the Study Advisory Group (SAG)																															Т	
Preliminary focus groups/online survey																																
First SAG meeting																																
Write the protocol																																
Design the questionnaires																																
Write strategy of analysis																																
Second SAG meeting																																
Design study database																																
Advertise the study																																
Test the data collection method																																
Submit final protocol for approvals																																
Advertise for reviewers																																
Start data collection																																
Run case reviewer meetings																																
Data analysis																																
Presentation to SAG and Reviewers																																
Presentation to Steering Group																																
Start writing the report																																
First draft to reviewers																																
Second draft to reviewers																																
Third draft to reviewers																																
Submit report to HQIP																																
Report design																																
Publish the report																																
Disseminate the findings																																



References

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12. Tim Cook & Jon Lund. 2021. Intercollegiate Surgical Curriculum Programme.

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