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INTRASCROTAL SWELLINGS: A SINGLE CENTER CROSS-SECTIONAL PROSPECTIVE OBSERVATIONAL STUDY ON CLINICOHISTOPATHOLOGICAL PROFILE WITH REFERENCE TO DIAGNOSTIC ULTRASOUND AND PUBLIC HEALTH IMPLICATIONS.

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Abstract

Background: Intrascrotal swellings are a pretty common entity faced by surgeons and surgical pathologists. The etiology ranges from inflammatory, infective to neoplastic proportions. Scrotal ultrasound (USG) plays a critical role in formulating management plan as many entities respond to conservative treatment without any need of surgical intervention.

Aims and Objective: The study was conducted to acquire an in-depth knowledge on varied presentations, public health implications and to evaluate the role of ultrasound imaging in the light of operative findings and histopathological examination (HPE) where definitive surgical management was carried out.

Materials and Methods: The study was conducted on one hundred voluntary participants presenting with intrascrotal swelling in the surgical outpatient and emergency units at a tertiary care center following approval of the institutional ethics committee and written informed consent and assent as applicable; excluding inguinal swellings, scrotal skin lesions and moribund patients. Clinicodemographic variables, imaging results, operative record and HPE findings were assessed, analyzed and correlated with appropriate statistical principles.

Results: Middle aged population between 30 and 60 years constituted the majority with a mean of 41.45 years of the study participants. Commonest intrascrotal pathology was vaginal hydrocele (62%), followed by epididymo-orchitis (40%). USG findings correlated with HPE results at a significance level of 0.05.

Conclusion: The study revealed scrotal USG as an important tool to guide management and identified key areas of public health concerns to initiate awareness campaigns.

Keywords: Varicocele, hydrocele, orchitis, epididymitis, seminoma, testicular tuberculosis, scrotal ultrasound.

Introduction

Background and rationale: The scrotum is a fibromuscular sac divided into two compartments by the median raphe. Each compartment contains a testis, epididymis, spermatic cord with fascial coverings. The pampiniform plexus is a network of many small veins found in the spermatic cord.[1] Each of these structures can be affected by a wide variety of pathology, including congenital, inflammatory and neoplastic processes.[2] According to Rubenstein et al, intrascrotal lesions continue to provide diagnostic challenge for physicians.[3] A diagnosis can be made with thorough history, physical examination and understanding of pathophysiological process of the structures within scrotum. Muttarak M et al have stated that a wide variety of scrotal conditions may cause painless swellings, many of which appear similar on physical examination.[4] While hydroceles, which are the commonest intrascrotal lesions, are usually benign; sometimes these may be secondary to testicular tumors. Again, testicular diseases, including malignancy, are not rare. Further, solid lesions of epididymis, though rarer, are more likely to be malignant. A wide variety of congenital remnants can also give rise to intrascrotal lumps, thereby broadening the differential diagnosis. Hence, investigations are often required to evaluate the lesions. Ultrasonography (USG) is a useful initial tool to differentiate between solid and cystic testicular and extratesticular masses, but imaging may not be adequate final diagnosis as Computed Tomography (CT) and Magnetic Resonance Imaging (MRI) scans are yet to be validated in this setting. Again, scope of Fine Needle Aspiration Cytology (FNAC) in the evaluation of intrascrotal swellings is limited. Therefore, histopathological examination (HPE) remains the mainstay modality for confirmatory diagnosis and tailored management.

Specific objective of the study is to analyze the presentation, anatomic distribution, efficacy of diagnostic modalities and epidemiologic considerations of various pathologies associated with intrascrotal swellings in an effort to emphasize and detect important public health implications to sensitize the policymakers and other stakeholders to formulate holistic guidelines.

Materials and methods

Study setting: This prospective, observational study was conducted over a span of fifteen months in a tertiary care center in the state of West Bengal, India after obtaining clearance for Institutional Ethics Committee, written informed consent and assent as applicable from voluntary participants who attended the outpatient door (OPD) of the hospital with intrascrotal lumps.

Study population, sampling method and sample size: From previous studies, a sample size of one hundred participants was considered adequate taking into account a dropout rate of ten percent. Participants were selected by simple random sampling with following criteria:

Inclusion criteria:

Scrotal swellings involving the spermatic cord, testis and tunica vaginalis.

Exclusion criteria:

1. Inguinal and inguinoscrotal swellings.
2. Swelling of the scrotal skin.
3. Postoperative collections.
4. Moribund patients.

Study technique: Details of patient's complaints, clinical findings and investigations were recorded in a specially designated format. The data were tabulated in a master chart which was subjected to appropriate statistical analysis.

Study tools:

1. Semi structured schedule or case record form.

2. Clinical examination records.
3. Appropriate investigations like hematological, biochemical and serological tests, USG and histopathological reports.

Study procedure:
A clinical diagnosis was attempted based on findings. Scrotal origin was confirmed by 'getting above the swelling test'. Elastic swellings surrounding the testis were tested for fluctuation and transillumination. Varicoceles were diagnosed on the basis of 'bag of worms' feeling in the cord. For firm to hard swellings, relationship to cord or testis, tenderness and other usual features of swellings were recorded. All patients underwent scrotal USG. Abdominal USG was done where intraabdominal mass lesions were suspected. All cases were individualized and prioritized for necessary conservative or surgical management in the follow up period. Complications, if any, arising out of clinical conditions or surgical interventions, were managed appropriately. Histopathological reports were considered confirmatory wherever any operative management was carried out.

Follow up protocol: Participants were advised to attend periodic follow up after a specified interval or on recurrence of symptoms.

Outcome assessment: The following parameters were studied and tabulated for statistical calculations:
1. Age of the participant.
2. Mode of clinical presentation.
3. Correlation of preoperative ultrasound findings with postoperative HPE.

Statistical analysis: Data were entered into a Microsoft excel spreadsheet and analyzed by SPSS Statistics for Windows, Version 25.0. Armonk, NY: IBM Corp (2017). Pearson's Chi-square test was applied wherever necessary. Alternatively, Fisher exact test was conducted when expected frequency in one cell of the 2x2 contingency table became less than 5. In larger contingency table where the expected cell value is less than 10, Yates' correction was applied. A significance level of 0.05 was chosen for calculation of *P*-value.[5]

Result
In the present study comprising one hundred participants, majority was middle aged between 30 and 60 years. The lowermost age was 13 years and the highest being 78 years with a mean age of 41.45 years. Commonest intrascrotal pathology was hydrocele affecting 62% study population, 49% as sole pathology and rest 13% with associated pathologies. It affected all age group after 20 years with maximum case load (41.9%) between 50 and 70 years. Epididymo-orchitis ranked second (40%). Other intrascrotal pathologies constituted minor proportions like seminoma being observed in the third decade and epididymal cyst in the fourth and fifth decades of life **[Table 1]**. Forty percent participants reported acute painful onset scrotal swelling and remaining sixty percent with a more gradual onset. All painful swellings had epididymo-orchitis either as sole entity or associated with epididymal cyst and/or hydrocele. Fever was present in 33% cases, with 93.9% having epididymo-orchitis either as sole or associated component. This was statistically significant at 5% level ($P<0.00001$) **[Table 2]**. Urinary complaint like dysuria was found in 9% cases with the majority (55.5%) having epididymo-orchitis solely or in combination. However, this association was not statistically significant ($P=0.5508$) **[Table 2]**. Preoperative ultrasound scanning emerged as an invaluable tool to diagnose various intrascrotal pathologies to accurately guide rational therapy, conservative or surgical, in the current study. Thickened and tender spermatic cord as an indication of epididymo-orchitis in 40% subjects and normal cord in the rest 60% with variable entities like varicocele, epididymal cyst and hydrocele was proved effective in key treatment decision making. One case of an enlarged heterogeneously hypoechoic nontender testicular lesion on ultrasound was

presumptively diagnosed as testicular tuberculosis which was subsequently proved by histopathology and cartridge based nucleic acid amplification test (CBNAAT) of the tissue extract. Another case of painless hard testicular mass appearing as lobulated hypoechoic lesion on USG was provisionally reported as seminoma, which after undergoing high inguinal orchiectomy proved so on HPE. Therefore, the association between preoperative USG diagnosis with that of postoperative HPE was statistically significant at 5% level (P<0.00001) **[Table 3]**.

Table 1: Age group wise distribution of intrascrotal pathologies.

Age group in years (N=100)	Hydrocele	EPDO	EPDO with Hydrocele	EPDO with Hydrocele and Epididymal Cyst	Testicular TB	Epididymal Cyst	Varicocele	Seminoma
10-19 (11)	0	6	3	0	0	2	0	0
20-29 (17)	7	6	2	1	0	0	0	1
30-39 (17)	7	8	1	0	0	1	0	0
40-49 (16)	6	2	1	1	1	2	3	0
50-59 (20)	13	3	2	1	0	1	0	0
60-69 (12)	10	2	0	0	0	0	0	0
70-79 (7)	6	0	1	0	0	0	0	0
Total (100)	49	27	10	3	1	6	3	1

Figures within parenthesis indicate the number of participants in the concerned age group. Abbreviations: EPDO (epididymo-orchitis), TB (tuberculosis)

Table 2: Clinical profile of intrascrotal pathologies.

Fever	EPDO	EPDO with other intrascrotal pathologies	Intrascrotal pathologies other than EPDO	Row total	Chi square value=64.5827, df=2 (Yates' corrected) P<0.00001 Significant at 0.05 level.
Present	24 (8.91)	7 (4.29)	2 (19.8)	33	
Absent	3 (18.09)	6 (8.71)	58 (40.2)	67	
Column total	27	13	60	100 (Grand total)	
Urinary complaint	EPDO	EPDO with other intrascrotal pathologies	Intrascrotal pathologies other than EPDO	Row total	Chi square value=1.1928, df=2 (Yates' corrected) P=0.5508 Not significant at 0.05 level.
Present	3 (2.43)	2 (1.17)	4 (5.40)	9	
Absent	24 (24.57)	11 (11.83)	56 (54.60)	91	
Column total	27	13	60	100 (Grand total)	

Figures within parenthesis indicate expected cell total. Abbreviations: EPDO (epididymo-orchitis), df (degree of freedom)

Table 3: Preoperative sonological profile with definitive diagnosis by histopathology.

USG finding	EPDO with other intrascrotal pathologies	Intrascrotal pathologies other than EPDO	Row total	Fisher exact test statistic value <0.00001 Significant at 0.05 level.
Tender and thickened spermatic cord	40	0	40	
Normal spermatic cord with associated findings	0	60	60	
Column total	40	60	100 (Grand total)	

Abbreviations: USG (ultrasonography), EPDO (epididymo-orchitis)

Note: In EPDO, thickened and tender spermatic cord is present on USG, while in other pathologies, it is absent. Hence, sonological features of respective pathologies devoid of EPDO component are

clubbed together and thickened tender spermatic cord is taken as reference for ease of calculation of *P* value to find association between the sonographic and histopathologic findings.

Discussion

Commonest form of presentation of intrascrotal swelling in the current study is hydrocele, 49% as sole and an additional 13% as associated pathology taking the total to 62%. The prospective study conducted among Brazilian population by Romero FR et al also presented it as a common lesion, but with a much lower prevalence of 13% with higher frequency over 60 years of age, particularly in diabetics or individuals with history of nonspecific urethritis.[6] Higher prevalence among Indian population may be attributed to lymphatic filariasis, a major public health problem in tropical countries. The study by Gyapong JO et al revealed a mean prevalence of 17.78%, where the community prevalence of microfilaremia correlated well with that of hydrocele.[7] These findings suggest that a more reliable and valid estimate of community burden of lymphatic filariasis can be obtained using the prevalence of hydrocele as a diagnostic index. The study by Mishra S et al showed that the filaria related antigens and antibodies found in the serum can be detected with equal sensitivity in hydrocele fluid that can be used to correlate serum immunodiagnostics of filariasis and help monitoring the filariasis elimination programme.[8] Stonier T et al in their study found epididymal cyst **[Fig 1]** as the most common finding (27%) among 228 participants, contrary to a much lower prevalence of 9% in the present study. However, the prevalence of hydrocele was only 11% being the second most common finding of the study.[9] Epididymo-orchitis (40%), commonest intrascrotal inflammation in the current study, presented as a painful acute onset event, combined with fever in 77.5% and dysuria among 12.5% participants. As per the study of Krieger JN, epididymitis arises as a reproductive tract disease caused by Chlamydia trachomatis or Neisseria gonorrhea and represents the commonest cause of acute scrotal swelling in younger men below 35 years of age.[10] This finding is concordant with the present study finding of 70% among under 40 age group. The study by Walker NA et al revealed that both epididymitis and orchitis normally coexist with isolated epididymitis being more common than isolated orchitis. Commonest pathogen in under 35 age group is Chlamydia trachomatis and Neisseria gonorrhea, while Escherichia coli being more prevalent in above 35 years. Acute testicular torsion is the most important differential diagnosis of acute testicular pain in younger men.[11] Higher prevalence of epididymo-orchitis in lower age group might be attributed to active sexual life. Twenty three out of forty participants of the present study subsequently responded to medical management, while the rest had to undergo some form of surgical intervention due to either higher stage of the disease or failure of response to conservative management. The study favored scrotal ultrasound as an effective tool for diagnosis, staging and formulating case-based management in acute epididymo-orchitis. The current study had a single patient with testicular tuberculosis **[Fig 2]**. The study by Chattopadhyay A et al revealed 7-22% of epididymo-orchitis patients as genitourinary tuberculosis cases and assumed greater relative importance in high prevalence regions.[12] As per Johnson WD Jr. et al, Mycobacterium tuberculosis usually extends from prostate to epididymis through vas deferens. Rarely, it may result from hematogenous or lymphatic dissemination from prostate or urinary bladder lesions, which in turn are secondary to renal lesions.[13] Therefore, a high index of suspicion should be kept for systemic origin when tuberculosis is detected in testis as the first site. Policymakers must take this into account to initiate awareness campaign. Varicocele **[Fig 3]** was found in 3% of the study population, however, the study of Belker AM reported a higher incidence of 8-22% in the general population and 21-39% of men attending male infertility clinics.[14] The study by Orda R et al revealed an increase in the mean diameter of dominant veins in the left spermatic cord during Valsalva, which increased from 4.5 mm to 5.7 mm, thereby quantitatively representing venous reflux.[15] Hence, ultrasound imaging and measuring spermatic cord veins at the inguinal canal can be recommended as an accurate screening procedure for diagnosis, clinical classification and assessment of treatment result of varicocele **[Fig 4]**. The study by Annoni F et al showed doppler sonography as a reliable method of detecting reflux due to venous valvular incompetence that occurs in varicocele.[16] The higher sensitivity and specificity of doppler

examination compared with thermography and angiography in addition to low cost and noninvasiveness made it the procedure of choice in the diagnosis of venous reflux in varicocele. From public health point of view, early diagnosis and management of varicocele is of paramount importance as it is commonly related to male infertility and intraabdominal malignancy, particularly involving the kidney with invasion into the renal veins and inferior vena cava. The current study had a solitary case of seminoma that remains an important differential in painless scrotal lesions. As per Boujelbene N et al, pure seminoma is a rare pathology in the young adult, often discovered at an early age.[17] However, the study by Alexander EJ et al revealed incidence of seminoma in the 3rd to 5th decade of life accounting for 50% of testicular germ cell tumors.[18] As per Jemal A et al, testicular tumors, 95% of which are germ cell tumors, are the most common solid malignancy affecting males between 15 and 35 years of age, although it accounts for only 1% of all cancers in males.[19] The study of Mottet N et al revealed clinical examination coupled with ultrasound testing as the cornerstone of a sensitive screening programme of testicular enlargement.[20] Surveillance policies offer the opportunity to detect early relapse, thereby avoiding morbidities and risks involved in the clinical management.

To conclude, the current study is unique considering the fact that no studies combining public health implications and evaluation of efficacy of diagnostic modalities in the detection and early management of scrotal swellings have been previously carried out. However, large scale multicentric trials involving larger cohort with longer duration of follow up is recommended to generate robust data that may be utilized to formulate effective public health guidelines.

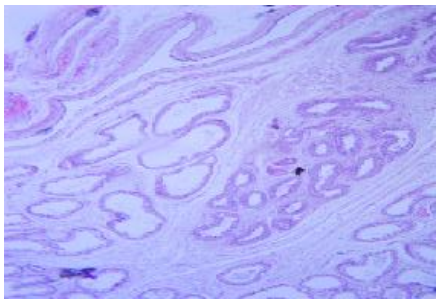

Fig 1: Epididymal cyst: Cyst wall lined by bland flattened cuboidal cells (H&E, 200X)

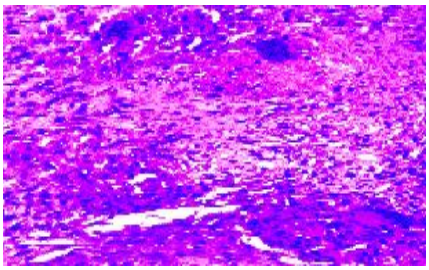

Fig 2: Testicular TB: Caseating granuloma with Langhan's type giant cells (H&E, 400X)

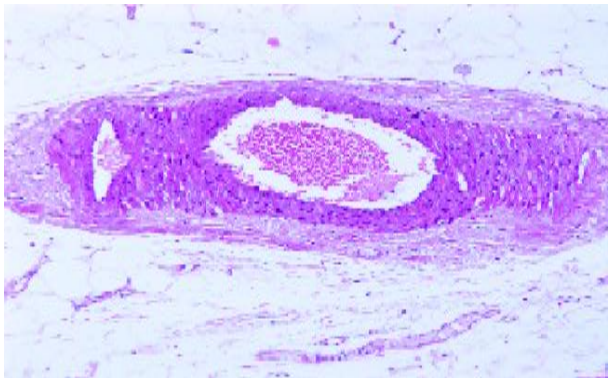

Fig 3: Varicocele: Thick walled congested and thrombosed blood vessels (H&E, 200X)

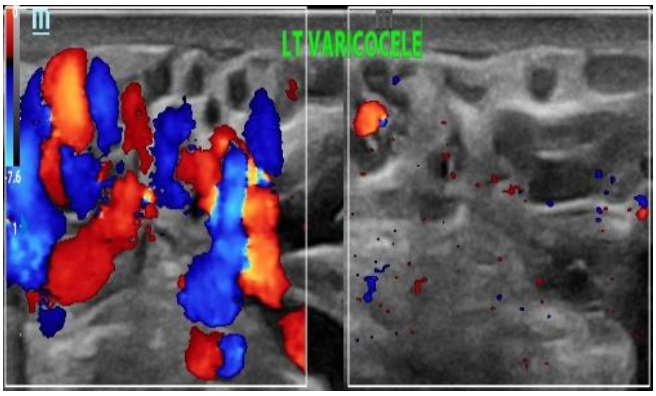

Fig 4: Varicocele: USG (Doppler and 2D) finding of dilated blood vessels above 2-3 mm diameter with flow reversal on Valsalva manoeuvre.

Author contribution:
1. NM: concept, design, literature search and data acquisition.
2. DD: concept, design and definition of intellectual content.
3. SG: statistical analysis, interpretation, manuscript preparation, drafting, revision for critical intellectual content, editing, review, communication and final approval of the version to be published.

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