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Original Research Article

The use of RMI in triaging benign pelvic masses from malignant lesions and facilitating their management

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ABSTRACT

Background: The most prevalent type of pelvic masses presenting to Gynec OPD are ovarian masses, which include cysts and tumors. Ovarian cancer is more common in older women, with highest incidence in seventies. Ultrasonography and surgically obtained tissue for diagnosis helps in optimising final plan. Good ethical practices suggest involvement of Gynec Oncosurgeon whenever necessary, after a correct preoperative diagnosis of pelvic masses is made. The basic diagnostic work-up of patients with a pelvic mass consists of a gynaecological examination, ultrasound and the analysis of serum tumour markers, especially CA 125. The objective of this study is to triage the patients and ensure optimum therapeutic approach for commonly encountered gynecological pelvic masses and to provide protocol-based treatment

Methods: Ours was a multicentric cross-sectional study in Navi Mumbai on "Patients presenting with abdominal masses" a combined, retrospective as well as prospective during the period of 6 months. 1st January 2023- 30th June 2023.

Results: The study group comprising of 140 patients in all, from 3 centres, were followed up from diagnosis till treatment comprising of namely: Gynec OPD at General hospital (10), a private MRI centre (30) and those admitted/attending Gynec OPD in Oncology hospital (100) with sonography findings of a pelvic mass greater than 6 cm size. Authors evaluated them on the basis of age, symptoms, and examination and tumor markers and managed as per RMI score to set a protocol.

Conclusions: With the help of ultrasonography findings and Ca125, the risk of malignancy index was calculated and helped us differentiate benign masses from cytology proven malignancy.

Keywords: Abdominal lump, Pelvic mass, Malignancy index, Gynaecological tumors, Adnexal mass, Ovarian tumour

INTRODUCTION

The most prevalent type of pelvic masses presenting to Gynec OPD are ovarian cysts and tumors.[1] The size of the mass, mobility, consistency, presence of solid components and associated pain are helpful in diagnosing the nature of the mass.

The 5 simple features that help to separate benign from malignant masses based on ultrasound parameters are bilaterality, tumor morphology, presence of solid areas, degree of vascularity and ascites.[2] Gold standard is always the histopathologic diagnosis of the adnexal mass.[3] The objective of this study was to triage the patient's risk-wise and to provide a protocol-based treatment.

Aim of the study

To draft a simplified protocol for management of abdominal masses based on the clinical presentation of patients and to screen malignant from benign lesions using the RMI score

METHODS

This was a multicentric cross-sectional study in Navi Mumbai on "Patients presenting with mass in abdomen", obtained from prospective as well as retrospective data. This study was conducted at Cancer hospital, General corporation hospital, and Diagnostic centre, all in Navi Mumbai from 6 months: 1st January 2023- 30th June 2023.

The prospective group

Comprised of fifty women presenting with a pelvic mass during the period of 6 months. These patients were followed up through diagnosis till treatment.

The study group comprised of 140 patients.

Inclusion criteria

Patients presenting with mass in abdomen who were either index cases or follow-up visits with prior registration before the study time. Patients referred on the basis of RMI.

Exclusion criteria

Exclusion criteria were pregnancy, renal tumors.

Table 1: Study groups.

Total of patients	Centre wise-study type	TATA ACTREC/TMH	Nerul general hospital	MRI Centre, Kharghar	Total
Number		10+90 = 100	10	30	140
Newly diagnosed	Prospective group	10	30	10	50
Old/ already diagnosed	Retrospective group	90	0	0	90

Table 2: Patients' complaints (some had overlapping symptoms).

S. no.	Patient's presenting symptoms	Number
1	Heaviness in lower abdomen	68
2	Irregular/abnormal menstrual bleeding (AUB)	44
3	Pain in abdomen	32
4	Urinary symptom acute retention, dysuria, increased frequency/hesitancy	21
5	Decreased appetite, weight loss	5
6	Bowel symptoms like: constipation/increased frequency	4
7	Fever	2

Regular follow-up without symptoms (as a routine after NACT—either pre-op or postoperative period).

Table 3: Emergency symptoms.

S. no.	Emergency symptoms	Management
1.	Acute abdominal pain (not relieved with oral medication)	Injectable analgesics
2.	Acute urinary retention	Catheterisation

The retrospective group

Included ninety cases of mass in pelvis diagnosed in the periphery and referred to the oncologist when RMI was >200. These patients had been under regular follow-up and they were monitored for their outcome during our study period.

These patients were evaluated and followed up till treatment in the study period

Patients who were referred to MRI centre with ultrasonography findings of a pelvic mass > 6 cm.

Research methodology: (developing a protocol)

Was developed in the prospective group. All, patients were managed symptomatically. After taking complete history, patients were triaged into four groups.

1. Acute presentation

Acute pain (torsion), degeneration of fibroid, Ruptured chocolate cyst, acute urinary retention by pressure of fibroid/mass, post-op pain/mass (hematoma)

2. Associated pressure symptoms

↑ urinary urgency/ ↑ frequency of defecation/ bloatedness.

3. *Slow onset symptoms*

Lump/mass in abdomen, heaviness, menstrual irregularities, loss of appetite, difficulty in breathing.

4. *Recurrence*

Mostly diagnosed with rising tumor markers, like Ca125.

Management protocol

The protocol was laid to stabilise the patient in case of acute symptoms e.g., those patients who had severe pain. If necessary, admission was advised. All patients with mass in pelvic region were evaluated for the nature of mass and followed up till cure

Ultrasonography of abdomen, pelvis was done. Those with pelvic mass were considered. If the size of mass was less than 6cm (i.e. >4 cm <6 cm) were called for a repeat scan after 4 months, assuming spontaneous resolution of benign simple/haemorrhagic cyst. If the size was>6cm, tumor markers were done and the risk of malignancy index (RMI) was calculated.

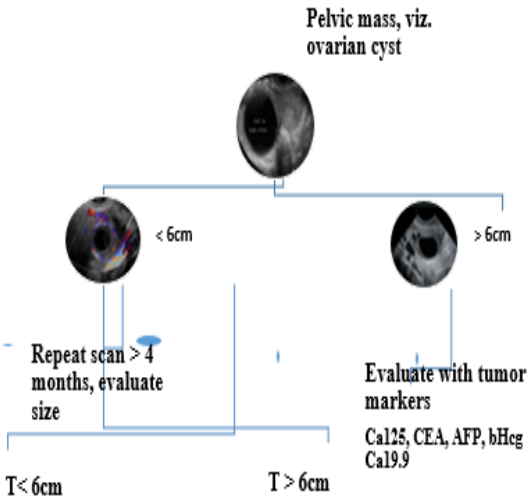

Figure 1: The protocol adopted is represented by the flow chart.

Calculate RMI, if >200: consider Malignant-- refer to Gynec Oncologist for definitive management for tissue diagnosis.

The ultrasonography of abdomen, pelvis was done with respect to the following so as to support/establish diagnosis stage the disease, size of mass, proximity to ureter/rectum/any other bowel structure, lymph node enlargement, involvement of adjoining structures/ capsular invasion, contralateral side pathology, free fluid calculates the RMI (risk of malignancy index): by assigning a score:

RMI=U×M×Ca125

U=The ultrasound result is scored 1 point for each of the following characteristics: multilocular cysts, solid areas, metastases, ascites and bilateral lesions

U = 0 (for an ultrasound score of 0), U = 1 (for an ultrasound score of 1), U = 3 (for an ultrasound score of 2 to 5).

M=If patient is premenopausal, M= 1, For postmenopausal women, M=3. The definition of 'post-menopausal' is a woman who has had no period for more than 1 year or a woman over 50 who has had a hysterectomy.[8]

If >200, consider Malignant, If <200, consider benign

RMI = U×M×Ca125

The American College of Obstetricians and Gynecologists (ACOG) has also released guidelines for assessing adnexal masses based on TVUS features, summarized below:

Benign

Simple cysts under 8 cm.

Malignant

Solid mass, septations >3mm, mural nodules, papillary excrescences, ascites (free fluid).

Indeterminate

Complex masses of any size, simple cysts > 8 cm.[2]

RESULTS

Total 40 patients were primarily seen in a general hospital (non-cancer) whereas 10 out of 100 patients studied from a tertiary Oncology centre, were benign. All had been most of which were already evaluated for malignancy by tumour markers and/or histopathologically diagnosed cases referred for completion surgery or neoadjuvant chemotherapy. Out of the 40 benign cases with pelvic masses, 11 patients were conservatively managed.

Table 4: Distribution of total 140 cases.

Type	Total	Benign	Malignant
Number	140	50=40+10	90
Percentage	100	35.71	64.28

Four of these were simple unilateral ovarian cysts measuring 5-6cm size with septation (U score =1) in premenopausal age group (M=1), with Ca-125 less than 35 (6, 18, 30, +9.5), thereby the RMI was absolutely in the benign zone (maximum 30) i.e. <200, suggestive of benign etiology. The mean Ca -125 was 28 amongst the benign tumors (confirmed on tissue diagnosis).

Table 5: The conservative as well as definitive management in benign lesions. in Charitable, general hospital and MRI centre: 40 cases.

S. no.	Diagnosis type	Number	Conservative management	Surgical management
1	Ovarian cyst			Cystectomy
	Mucinous cystadenoma	1		Exploration
	Reproductive age group	5		
2	Fibroid/s uterus			
	Single large/ multiple	7	Bladder drained by simple rubber Catheterisation (one case)	Myomectomy (later)
	Prolapsed endometrial polyp	2		Excision, vaginal polypectomy
	Focal fibroid with adenomyosis	7		TAH
3	Adenomyosis	3		
4	Adnexal mass			
	Chronic unruptured ectopic with superimposed infection	1		Exploratory laparotomy and excision of mass
	Inflammatory origin: hydrosalpinx	2	Inj. Placentrex, IV antibiotics	
5	AV malformation/retained POCs	1	Inj. Tranexamic acid, Inj. Methotrexate	
6	Ca endometrium	3		Pan Hysterectomy
7	Ca cervix	2		Wertheim's Sx
8	Hydronephrosis+/- hydroureter	2	IV fluids given for Hydrotherapy of renal cal (ref to surgeon)	
9	Severe endometriosis both ovaries cyst	1	Dilatation, curettage + LNG IUS insertion	
10	Perianal lipoma	1		Surgical excision (ref to surgeon)
11	Inguinal hernia	1		Ref to surgeon
12	Mullerian anomalies	1	Counselling	Ref for Lap hysterolaparoscopy
	Total	40		

Table 6: The operative management in malignant cases included radical surgeries.

Type of surgery		No.
Debulking surgery	Pri CRS	3
	IDS	51
	Trial resection*	7
	Post. Exenteration	2
	With Diversion stoma*	3
	IDS + IPEC	1
	With cholecystectomy*	6
Open Sx staging		4
MIS+Sx staging		3
Robotic Sx+ staging		3
Completion surgery		3
Exp Lap + Frozen sec		30
Few patients had two or more surgeries concurrently		
Total		100

*These surgeries were combined with debulking—primary cytoreductive surgery (CRS) or Interval debulking surgery (IDS) and cholecystectomy on the basis of RMI and clinical diagnosis, presence of dense colonic adhesions/ involvement of rectosigmoid / frozen section report and elevated tumor marker Ca19.9 respectively.

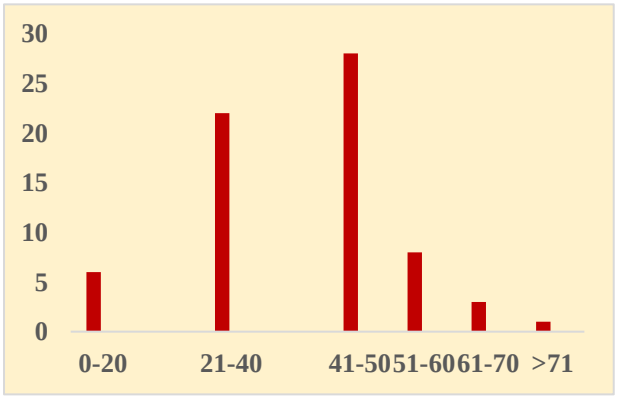

Figure 2: Age-wise distribution of cases.

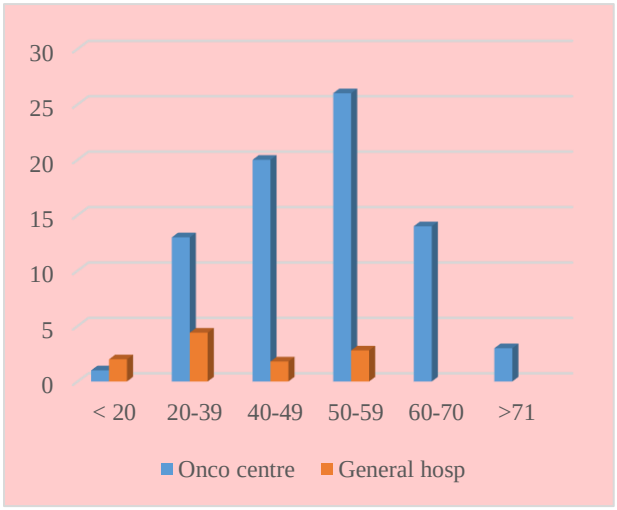

Figure 3: The age-wise incidence of cases with high RMI.

Therefore, managed conservatively on outpatient basis, although initial pain relief was through injectable NSAIDs. Two patients had renal calculi and presented with flank pain. Sonography of the abdomen revealed mild hydronephrosis, were relieved with injectable NSAIDs and Drotaverine intramuscularly.

Two patients were post-operative with wound inflammation, one referred with post Caesarean (22 days before) collection in pelvis and the other was post hysterectomy 5.8×3.5 cm sized inflammatory lesion in the right angle of vault. Since both these pelvic collections, were organised tissue reactions and did not have significant vascularity, we offered conservative management and the patients were discharged on 9th and 7th days respectively with regressing trend. The size shrunk to <2 cm, in 3 weeks.

Two patients presented with acute urinary retention and a distended urinary bladder, which needed urgent drainage. One of them had a 6×7 cm broad ligament fibroid causing pressure on ureter. She was operated for myomectomy, as early as possible; the other went to native place and was lost to follow-up.

One patient with severe endometriosis, frozen pelvis with kissing ovaries and the entire pelvis appeared adherent around paracervical region leading to acute on chronic pelvic pain. She was given IV antibiotics and anti-inflammatory and discharged after one week.

These surgeries were combined with debulking-primary cytoreductive surgery (CRS) or Interval debulking surgery (IDS) and cholecystectomy on the basis of RMI and clinical diagnosis, presence of dense colonic adhesions/ involvement of rectosigmoid/ frozen section report and elevated tumor marker Ca19.9 respectively.

Tissue diagnosis after surgery confirmed 10 patients out of total 100 cases were non-malignant as per histopathology report traced later.

The following graphs indicate the age-wise distribution of total cases with pelvic masses. The RMI was high in the 40+ age group in the onco group. Whereas in the general side, there was a bi-modal peak in third and fifth decades of life, as shown in the bar diagram.

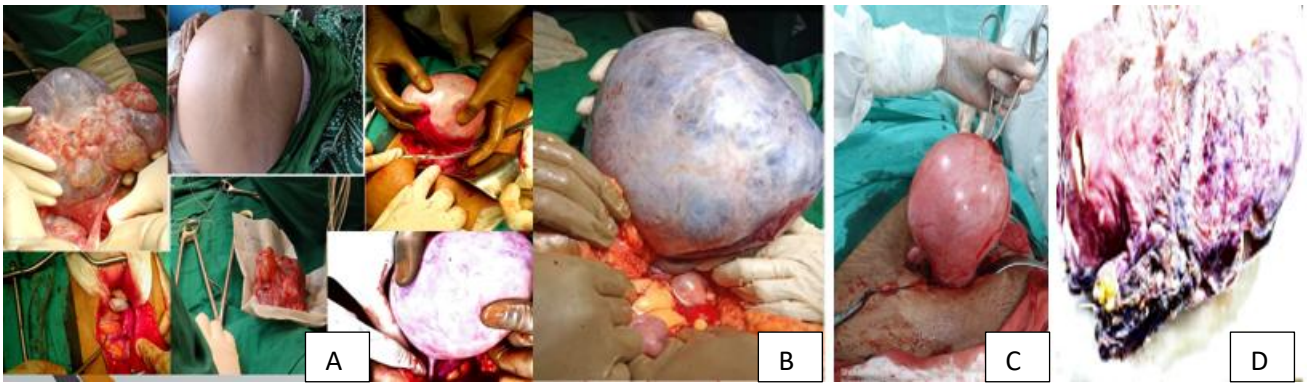

Figure 4 (A-D): Various pelvic tumors. Intra-operative pictures and pathology specimen.

DISCUSSION

Ovarian cancer is more common in older women, with the highest incidence in women in seventies.[5] The incidence of pelvic masses in our study was highest in the 40+ age group. This included both benign as well as malignant cases. According to a study in Turkey by Erhan and Riza et al, the incidence of malignancy was 24% in the pre-menopausal group and up to 60% in the postmenopausal women.[7]

Despite advances in chemotherapy, the prognosis of ovarian cancer is poor, as it is diagnosed in stage 3 or 4.5 It is called a 'silent killer', as the disease usually does not produce any obvious symptoms in early stages and there is no effective screening program to date.[8]

Managing adnexal masses is challenging to the obstetrician for deciding whether the procedure is optimal, radical surgery versus minimally invasive operations to minimise trauma, yet remove the disease in toto, the fear of leaving a residual disease vis a vis a 'conservative approach'.[10] Staging laparotomy provides a balance as a look and decide option in select cases where low vascularity on ultrasound and non-complex, simple but big size borderline tumor.[4] Thus, the most useful criteria were a serum CA 125 level of 30 U/ml (sensitivity 81%, specificity 75%) and an ultrasound score of 2 (sensitivity 71%, specificity 83%). In our study, both RMI as well as MIS (Clinical staging) in borderline cases have been helpful in management of pelvic masses measuring more than 6 cm in size and following them up over 3-4 months depending on associated risk factors…similar to the study by Garima et al, Surendra et al in 2013.[6]

In 1990, Jacobs and associates discovered a risk scoring system based on menopausal status, CA125 levels and ultra-sound characteristics with a sensitivity of 85.4% and specificity of 96.9% when cut-off was 200. This was original RMI 1, (Risk of malignancy index 1) which was modified by the ultrasound score later on by Tingulstad who devised RMI2 in 1996, RMI 3 in 1999 and in 2009 Yamamoto further came up with RMI4, that included the tumor size in the score. Consequently, there has been vigorous research into ovarian cancer screening methods, one of which is the risk of malignancy index (RMI), which is now also upgrading to RMI 1-49.

The IOTA-Adnex model which has 'set' criteria purely on ultrasonography features does not consider Ca-125 and yet claims to be much more sensitive in identifying malignant lesions.[3]

In the retrospective arm, we had patients referred with either high RMI or with tissue diagnosis, for completion surgery or secondary interval debulking, after administration of chemotherapy. Therefore, we could not take a mean of the RMI in the proven malignant cases. In most of the cases, Ca125 was considered as a measure of the follow-up.

Table 7: RMI 2 Vs RMI 1 classification.

RMI		
RMI 1[4]	1 if premenopausal 3 if postmenopausal	0 if no abnormality 1 if one abnormality 3 if ≥ 2 abnormalities
RMI 2[5]	1 if premenopausal 4 if postmenopausal	1 if ≤ 1 abnormality 4 if ≥ 2 abnormalities

Also, it is noteworthy that RMI is only a guide; therefore, patients with a family history of ovarian and/or breast cancer or any malignancy need further evaluation irrespective of their RMI score.[5]

In place of the conventional RMI, using RMI 2 may offer an upper edge in increasing sensitivity as well as specificity, in identifying malignancy cases 1.

In RMI 2, U is 1 if there are 0–1 abnormal finding and is 4 for 2 or more abnormal findings. M would be 1 for pre-menopausal women and 4 in post-menopausal women.[7]

CONCLUSION

RMI has been a useful and applicable method for initial assessment of patients with pelvic masses which would help gynaecologists to identify women with high probability of malignancy because of its high specificity, thereby, facilitating indicated referrals to gynaecologic oncologists. Both RMI as well as MIS (Clinical staging) in borderline cases have been helpful in management of pelvic masses measuring more than 6 cm in size.

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