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Audit Changes Clinical Practice! Impact on Rate of Justification of Hysterectomy Indication

Pages with reference to book, From 208 To 212

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Abstract

After performing a baseline audit in 1986-89, an ongoing quality assurance process was initiated in January, 1990 and all hysterectomies performed over the next 2 year period were analyzed. Hysterectomy indications were divided into two groups: one in which the uterine specimen was expected to show pathology and another in which no pathology was expected. The hysterectomy was considered justified in the former if the pathology report verified the indication or showed a significant alternate pathology. In the latter, validation criteria showing documentation of certain prerequisite diagnostic procedures performed before reverting to hysterectomy, were used to ascertain justification. The overall rate of justification in the ongoing audit was 96%, being 97% for the group where hysterectomy indication was potentially confirmable by pathologic study and 93% for the one where it was not. Comparison with baseline analysis showed that the justification rates were higher for all indications not potentially confirmable by pathologic study (93% vs 89%, $p < 0.05$), for recurrent uterine bleeding (90% vs 83%, $p < 0.05$) and for leiomyoma (97% vs 95%, $p < 0.05$). The improvement was associated with less frequent use of multiple indications in the ongoing study (10% vs 16%, $p < 0.05$). The justification rates for hysterectomy indication can be improved by prospective audit and by avoiding use of multiple indications (JPMA 45:208, 1995).

Introduction

Comparison of actual practice with that of an established ideal forms the conceptual basis of a clinical audit, but what is ideal treatment? There is support for clinical judgement as the final arbitrator of correct patient management, but some gynaecologists are known for acting liberally on the principle "If in doubt, cut it out" irrespective of the fact that the pathology might lie in the cerebrum rather than the pelvis¹. So, is subjective opinion of one clinician adequate? One is faced with these kinds of questions when one attempts to review patient's medical records for evaluation of appropriateness of hysterectomy. Such an audit becomes even more important when one realizes that hysterectomy is reported to be associated with 1-5/1000 mortality rate and 20- 50% morbidity rate^{2,3}. This would be unwarranted if the hysterectomy was not originally indicated. Objective justification for main of the generally accepted indications for hysterectomy is provided by a few reliable studies. We recently reported a retrospective analysis on this subject⁴, showing that hysterectomies were justified in 92% cases. Deficiencies were highlighted by the frequent use of multiple indications and lower rates of justification for hysterectomy indications not confirmable by pathologic study. Similar studies have revealed 85-95% rate of justification^{5,6}. The quality of care as judged by this comparison was adequate but there was room for improvement. As audit and quality assurance is being emphasized increasingly for purposes of improving patient care^{7,8}, we introduced a criteria-based audit for justification of hysterectomy. The quality assurance process used for this audit requires selection of a primary preoperative diagnosis from a standard list, for which justification criteria were developed by consensus of the consultants working in the department. The impact on quality of care is studied by comparing the results of the first 2 year analysis with those of a baseline audit carried out at the same

hospital.

Subjects and Methods

The Aga Khan University Medical Center is a private teaching hospital providing general and tertiary care to a largely self-referred population. The department of Obstetrics and Gynaecology is composed of 10 practicing specialists and there is an accredited residency training programme. The hospital has a staffed quality assurance committee that meets periodically to discuss hospital-wide quality issues. A focused audit on justification of hysterectomy indications was performed 2 years after initiating a criteria-based quality assurance process to analyze its impact during the study period from January, 1990 to December 1991. The indications for hysterectomy, as described in our previous report⁴, were divided into two groups: A pre-operative diagnosis in the first group had an anatomic or histologic basis and one in the second group was a description of a sign or symptoms which may or may not have associated his topathologic abnormality as shown below:

1. Diagnosis potentially confirmable by pathologic examination e.g., leiomyoma, preinvasive and invasive gynaecologic disease, endometriosis, adnexal mass, pelvic infection, adenomyosis and others with potential of serious outcome.
2. Diagnosis not potentially confirmable by pathologic examination e.g., recurrent uterine bleeding, chronic pelvic pain, uterovaginal prolapse, pregnancy catastrophe and others with potential of serious outcome.

The decision to perform a hysterectomy was made by a consultant. A single preoperative diagnosis or a primary diagnosis in case of multiple reasons was indicated. If the preoperative note stated multiple indications without pointing, out the dominant diagnosis, the records were evaluated individually to choose the most appropriate single diagnosis based on the presenting signs, symptoms and preoperative investigations in each case. The operation was performed by a consultant or by a registrar/senior resident under a consultant's supervision. The operative specimen was studied grossly and microscopically by a consultant pathologist. All data (preoperative note and histopathology report) were collected prospectively. In order for the hysterectomy to be considered justified in the first group, the pathologic examination of the hysterectomy specimen was required to reveal the same pathology as preoperatively indicated (verification of indication) or other significant pathology instead. For leiomyomata to be considered justified it had to be at least 12 gestational weeks in size or symptomatic or distorting the uterine cavity. Adenomyosis was, defined histologically as invasion of more than one third of myometrial wall thickness. In the second group "Validation Criteria" (Table 1),

Table I. Validation criteria used for the indication where pre-operative diagnosis was not potentially confirmable by pathologic study.

Indications	Pre or intra-operative note
Recurrent uterine bleeding	<p>* Documented attempts at control through hormonal therapy and at least one D&C.</p> <p>* Irregular, heavy bleeding requiring extra protection for more than one year in a patient age 35 or above.</p> <p>* Severe anemia due to continuous bleeding where patient compliance in the judgement of the surgeon was expected to be poor.</p>
Uterovaginal prolapse	<p>Documented symptoms of discomfort and significant uterine prolapse on digital vaginal and per speculum examination.</p>
Pregnancy catastrophe	<p>Documented extreme urgency based on continued blood loss.</p>
Chronic pelvic pain	<p>Documented no significant pathology on laparoscopic examination with failure of therapeutic trial with non-steroidal anti-inflammatory drugs or diuretics or contraceptive pill and negative effect on patient's life.</p>

*** Presence of any one sufficient for validation.**

showing a documentation of certain pre-requisite diagnostic procedures performed before reverting to hysterectomy, were used to ascertain justification. Such validation criteria were the same as those for the baseline study⁴. The parameters studied were age, parity, multiplicity of indications, type of hysterectomy, conservation of ovaries and justification of indications. For the purpose of comparison data from a baseline analysis during 1986-89⁴, were used as control. Chi-square test with Yates correction was used for analysis of difference between proportions. A p value of <0.05> was taken as significant.

Results

Table II. Justification of hysterectomy indication in study population (1990-91).

Indication (No. of cases)	Verified/ Validated. No.	Alternate Pathology No.	Hysterectomy Justified	
			No.	%
Potentially confirmable by pathologic study				
All indications (193)	151	37	188	97.4
Leiomyoma (112)	88	21	109	97.3
Gynaecologic malignancy (10)	10	-	10	100
Pre-malignant condition (5)	4	1	5	100
Adnexal mass (32)	22	8	30	93.7
Endometriosis (8)	4	4	8	100
Adenomyosis (21)	18	3	21	100
Pelvic infection (2)	2	-	2	100
Adjacent cancer (3)	3	-	3	100
Not potentially confirmable by pathologic study				
All indications (133)	124	-	124	93.2
Recurrent uterine bleeding (73)	66	-	66	90.4
Uterovaginal prolapse (48)	48	-	48	100
Pregnancy catastrophe (10)	10	-	10	100
Pelvic pain (2)	0	-	0	0
Total (326)	273	39	312	95.7

Table II shows the indications of hysterectomy and their justification during the period 1990-91. Of the 236 hysterectomies, 193 were performed for a diagnosis that potentially could be confirmed by pathological examination. The remaining 133 had a pre-operative diagnosis that was not confirmable. A total of 312 (95.7%) indications were justified, 188 (97.4%) being justified in the group where pathology was expected and 124 (93.2%) in the group where pathology was not expected. The single most common indication was uterine leiomyoma stated in 112 patients. Of these, 24 cases showed no leiomyoma on pathological examination. In order for a leiomyoma to be considered significant, it had

to be either at least 12 gestational weeks size or symptomatic or distorting the uterine cavity. Out of these 24 cases, 21 had significant alternate pathology e.g., adenomyosis, which had been confused for leiomyoma preoperatively. Taking these into account a total of 109(97.3%) hysterectomies were justified. Gynaecologic malignancy included 10 cases, six of which were for cervical cancer and four for endometrial cancer. All of these were verified. Gynaecological pre-malignant conditions included 5 cases, all involving the cervix. Thirty-two cases were operated on for adnexal masses and the indication was considered justified when an ovarian malignancy or a large leiomyoma or endometriosis was found. Hence, a total of 93.7% of hysterectomies in this Group were justified. Hysterectomies were performed for adenomyosis in 21(6.44%) cases. Post-operatively this diagnosis was verified in 18 cases (85.7%). Allowing for significant alternative pathology, the justification rate became 100%. The second most common indication was recurrent uterine bleeding for which 73 uteri were removed. In 66 of these cases, the indications were justified according to the criteria outlined in Table I. Out of these hysterectomies 49 were performed after a documented failed trial of hormones and dilatation and curettage. However considering other criteria outlined in table IV a total of 66 (90.4%) of cases were justified. On pathologic examination of these specimens, adenomyosis was present in 44 (62.27%) cases and uterine leiomyomas were seen in 16 (21.91%). The rest of the cases with significant pathology showed endometrial hyperplasia in 5 cases and endometrial cancer in one. Uterovaginal prolapse was noted in 48 cases, all of which were justified.

Table III. General characteristics of control and study groups₁

Characteristic	Control Group+ (n=376)	Study Group# (n=326)
Age (Years)		
mean	45.2	44.5
Parity (Nulliparous)		
No.(%)	15 (4.3%)	10 (3.1%)
Multiple indications		
No (%)	61* (16.2%)	33 (10.1%)
Type of procedure		
Vaginal		
No (%)	49 (13%)	52 (16%)
Abdominal		
No (%)	327 (87%)	274 (84%)
Simple	319	260
Radical	2	4
Sub-total	6	10
Ovarian conservation		
No (%)	270 (71.8%)	226 (69.4%)

***Higher than study group (p<0.05)**

+Baseline study 1986-89 (Rizvi et al., 1991)

Ongoing quality assurance 1990-91.

Table III shows the general characteristics of control and study groups. The control group was matched for all characteristics except use of multiple indications which was higher as compared to study group (16% v 10%, p <0.05).

Table IV. Hysterectomy indications in control and study groups by single pre-operative diagnosis*.

Indication	Control Group+ (n=376)		Study Group# (n=326)	
	No	(%)	No	(%)
Potentially confirmable pathologic study				
All indications	250	(66.5)	193	(54.2)
Leiomyoma	164	(43.6)	112	(34.4)
Gynaecologic malignancy	12	(3.2)	10	(3.0)
Pre-malignant condition	3	(0.8)	5	(1.6)
Adjacent cancer			3	(0.9)
Adnexal mass	30	(8.0)	32	(9.8)
Endometriosis	10	(2.6)	8	(2.5)
Adenomyosis	28	(7.5)	21	(6.4)
Pelvic infection	3	(0.8)	2	(0.6)
Not potentially confirmable by pathologic study				
All indications	126	(33.5)	133	(40.8)
Recurrent uterine bleeding	83	(22.1)	73	(22.4)
Uterovaginal prolapse	36	(9.6)	48	(14.7)
Pregnancy catastrophe	5	(1.3)	10	(3.1)
Others	2	(0.5)	2	(0.6)

*A single pre-operative diagnosis or the most dominant diagnosis in case of multiple indications (Controls n=61; Study n=33)

+Baseline study 1986-89 (Rizvi et al., 1991)

Ongoing quality assurance 1990-91

Table IV shows the indications for hysterectomy in control and study groups. The control group was matched for all indications to study group. The impact of a prospective quality assurance process is shown in Table V.

Table V. Number and percent of justified hysterectomy indications in control and study populations.

Indication	Control Group+		Study Group#	
	No	(%)	No	(%)
Potentially confirmable by pathologic study				
All indications	235/250	(94)	188/193	(97)
Leiomyoma	156/164	(95)*	109/112	(97)
Pre-malignant condition	3/3	(100)	5/5	(100)
Adnexal mass	27/30	(90)	30/32	(94)
Adenomyosis	24/28	(86)	21/21	(100)
Not potentially confirmable by pathologic study:				
All indications	111/126	(89)*	124/133	(93)
Recurrent uterine bleeding	69/83	(83)*	66/73	(90)
Total	346/376	(92)	312/326	(96)

*Lower in control group ($p < 0.05$)

+ Baseline study 1986-890 (Rizvi et al., 1991)

Ongoing quality assurance 1990-91

The overall justification rates were improved in this study as compared to the baseline rates (96% vs 92%, $p < 0.05$). The overall high rate of accompanied by significantly better rates for all indications not potentially confirmable by pathologic study (93% vs 89%, $p < 0.05$), for recurrent uterine bleeding (90% vs 83%, $p < 0.05$) and for leiomyoma (97% vs 95%, $p < 0.05$).

Discussion

Hysterectomy is one of the most common operative procedure performed in women of reproductive age^{9,10}. The medical, emotional, sexual and economic consideration related to removal of the uterus are complicated by religious, cultural and financial pressure on patients and their families. When performed appropriately, hysterectomy leads to patient's satisfaction and praise, but this is not always the case. Several questions about the indications, probable overuse and justification of hysterectomy have been raised^{6,11,12}. Quality assurance programmes have been shown to have a healthy impact on quality of patient care by decreasing the frequency of hysterectomy and increasing its confirmation rate^{13,14}. Evaluation of appropriateness of hysterectomy should be an integral part of an audit. Appropriateness can be defined as the degree of correlation between a condition and the action taken to improve it. Justification of hysterectomy indication thus becomes its valid measure⁷. The indications for hysterectomy, however, vary from benign conditions like uterovaginal prolapse to pre-malignant

and malignant conditions like those of the cervix, to life threatening situations like uterine rupture^{11,12}. Lack of an acceptable list of indications may lead to overuse of the procedure¹³. In many cases the accuracy of preoperative diagnosis cannot be established⁵. The problem of defining a hysterectomy indication is not only complicated by the numerous lists documented in literature, but also by the use of combinations of several indications, any one of which alone would be insufficient for justification of the procedure¹¹. The use of multiple indications has been associated with lower justification rates¹⁵. Hence, in this study the surgeon was required to clearly indicate a primary diagnosis in the preoperative note which could later be verified or validated, Efforts to validate the preoperative indications 'for hysterectomy are further complicated by the general lack of agreement over the definition of "necessary" This is because quality of life considerations including a negative effect on daily routines, fear of unintended pregnancy, stress of dysmenorrhea etc. have an important contribution in the decision to remove a uterus, and all uteri removed are not expected to show an abnormality detectable by presently available histopathologic techniques. For such indications there was lack of suitable validation criteria in the past¹². We resolved these issues by developing a system of reviewing two relatively brief documents i.e., surgeons preoperative note and histopathology report, to monitor the appropriateness of hysterectomy - when pathologic tissue was expected in the surgical specimens, the indication could be verified by the pathology report and when no pathologic tissue was expected the indication could be validated if certain criteria (Table I) had been satisfied in the preoperative note. This system resulted in improved justification rates for hysterectomy indications as shown in Table V. This change could be attributed to the differences in type of patients admitted and the attending surgeons during the two periods that were analyzed. The former is unlikely because there were similarities of age, parity, predominance of abdominal type hysterectomy, trend of ovarian conservation and most common indications in the control and study groups (Tables III and IV) For the latter, there was no change in the two studies. The lower use of multiple indications in the study group (Table III) may have been a result of the increased awareness of its deficiencies highlighted by the baseline study at the same hospital⁴ before initiation of the audit. Hence, the improvement can be attributed to reduction in use of multiple indications, use of feedback and increased awareness on the part of surgeons participating in the study. Medical audit should ideally be based on randomized clinical trials. In the absence of such data other methods like obtaining consensus opinion¹⁶ may be applied. We resorted to use of present criteria to judge the appropriateness of treatment in relation to signs, symptoms and investigations as described in "methods". One could argue that such guidelines developed by an expert panel depend entirely on the panel members. So, such a consensus view cannot reflect the views of other experts, but is universally essential in this matter? The art of providing appropriate medical care could become extremely difficult if one attempted to achieve worldwide agreement. We believe that audit ratings of justification of hysterectomy indication based on consensus criteria are preferable to an audit in which the only arbitrator of correct management is clinical judgement of one individual, The system of reviewing two sample records i.e., preoperative note and histopathology report provides an efficient means of ongoing quality assurance and the justification rates can be improved by a prospective audit in which use of multiple indications is avoided. It is possible to educate clinicians to be more critical in their decision-making and to change their clinical practice.

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