

Original Research Article

Cost-utility analysis of outpatient department based small biopsies for diagnosis of gynecological cancers: a single centre study

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ABSTRACT

Background: The financial toxicity of treating cancer is exorbitant and health insurance schemes such as the Ayushman Bharat Pradhan Mantri Arogya Bima Yojna, have a great impact in mitigating this difficulty. However, package reallocation can be considered for certain surgical procedures that can be performed on an out-patient basis without requirement of admission. This study was conducted with aim of assessing cost-utility of small biopsies compared with the tier 3 to tier 1 package provided in the PMJAY scheme. The study has relevance and significance to the Indian population and similar populations in the low-middle income or even high-income countries, where the public health insurance system is implemented.

Methods: This study compares the cost-utility of performing out-patient diagnostic procedures with those performed in the daycare/in-patient setting, with or without utilization of the public health insurance package. The accuracy of the procedure was assessed for biopsies performed on 145 patients evaluated in the out-patient department (OPD) in 2 years. The accuracy of small biopsy in confirmation of diagnosis and its role in decision making was assessed.

Results: The study found high accuracy of outpatient procedures in confirmation of diagnosis of gynecological malignancies while being very cost-effective.

Conclusions: This analysis concludes that OPD based biopsies or office procedures are very cost-effective and can significantly and positively impact out-of-pocket expenditure for patients seeking cancer treatments, while saving the costs in the insurance scheme packages.

Keywords: Office biopsy, Out-patient care, Cost effectiveness, Health insurance

INTRODUCTION

The socioeconomic impact of cancer diagnosis and treatment is significant and health insurance schemes have been useful in deflecting some of the crippling effects of such expenditure on cancer patients and their families. The expenditure on healthcare is predominantly out of pocket for patients in the region of Uttar Pradesh and health insurance schemes like the Pradhan Mantri Jan Arogya Yojna (PMJAY) are expected to mitigate this financial toxicity affecting most of the eligible population especially for those suffering from cancer.^{1,2} The health scheme

offers treatment packages under various specialty-based treatment protocols and the cost of biopsies if applied ranges from 2000 to 7000 Indian National Rupee for simple procedures like tissue biopsy from gynecological sites (cervical, endometrial, vagina or vulva).² Most of these procedures can be performed under local anesthesia in the out-patient department while clinically evaluating the patient.^{3,4} Histopathological diagnosis of cancer is not only required for confirmation and classification of the cancer but is also now essential for informing treatment in the era of molecular and immunohistochemical diagnostic markers.^{5,6} The same tissue is also amenable to genetic

testing and the newer treatment approaches depend heavily upon this information.⁶ Thus, obtaining timely and adequate biopsy is the cornerstone of treatment initiation in cancer.⁷ The accuracy and to cost-effectiveness of OPD based biopsy methodology of patient evaluation and diagnosis, also known as office procedures for gynecological cancers, was assessed for consideration of reallocation of budget in the PMJAY packages, that may be better utilized for other procedures or medications.

METHODS

This was a retrospective comparative study of cost-utility where costs of biopsy procedures performed as part of routine outpatient care, from March 2022 to December 2024 were included in an analysis of accuracy and cost-utility. The baseline accuracy was assumed as 85 percent for calculation of sample size which was 200. Patients presenting at Kalyan Singh Super Specialty Cancer Institute, a public sector teaching institute, in Lucknow, gynecological oncology OPD with suspected cervical, endometrial or vulval cancer were included. The intervention under study was small biopsy (defined as 1cm or less single bit of tissue or <2 cm cumulative tissue if multiple bits of tissue) procedure for cervix, endometrium and vulva performed in OPD in maiden hospital visit, which is reviewed by two independent pathologists as routine protocol in department of pathology. Patients of suspected premalignant and malignant lesions of cervix, endometrium and vulva, aged more than 18 years, amenable for cancer directed treatment other than best supportive care, patients willing for biopsy and further treatment and follow-up in the institute, were included in the study. Those with poor performance status (ECOG and GCS), eligible for best supportive care only, were excluded from analysis.

The instruments used for biopsy were reusable and sterilizable such as the Tischler's biopsy forceps for cervix and vagina, the Novaks biopsy curette for endometrial biopsies and the Keyes biopsy forceps for the vulval

malignant and pre-malignant lesions. The Pipelle's disposable curette was also used in some patients. The range of tissue samples was largest single bit of 1 cm and smallest 5 mm for cervix/vagina/vulva. Endometrial tissue was sampled as 2 ml to 5 ml of endometrial tissue collection mixed with clots and mucous.

Retrospective and prospective data of reports and treatment outcomes was collected from hospital records. The histopathological accuracy was checked with the specimens obtained after surgery, where surgery was the primary treatment. For those who did not undergo surgery, the re-biopsy rate was considered for accuracy. The cost effectiveness analysis included only direct cost of diagnostic procedure and histopathology reporting charges. Indirect costs of number of visits, loss of wages and duration of hospital stay were excluded from ICER analysis. It was considered that admission to avail diagnostic procedure package under the PMJAY scheme would incur additional direct and indirect cost of a greater number of visits and loss of wages for patient or accompanying next of kin, apart from admission charges, which was not the case in the OPD setting.

Statistical analysis

The cost effectiveness threshold has been described in US dollars considering the hospital charges of a tertiary care multispecialty cancer treating facility of the public sector in a tier 1 city and compared with the package of the widely applicable PMJAY scheme. Cost effectiveness modelling and analysis was done through an online calculator of the Value Analytics Lab (<https://www.valueanalyticslabs.com/cost-effectiveness-analysis/>). Three strategies were included in this analysis. Strategy 1 lowest cost package, strategy 2 highest cost package of the PMJAY and strategy 3, the OPD based biopsies. The QALYs were considered same for all three strategies at 0.8, since these are diagnostic interventions and do not directly affect the gain in life years. The cost-effectiveness threshold was considered at 89 USD.⁸

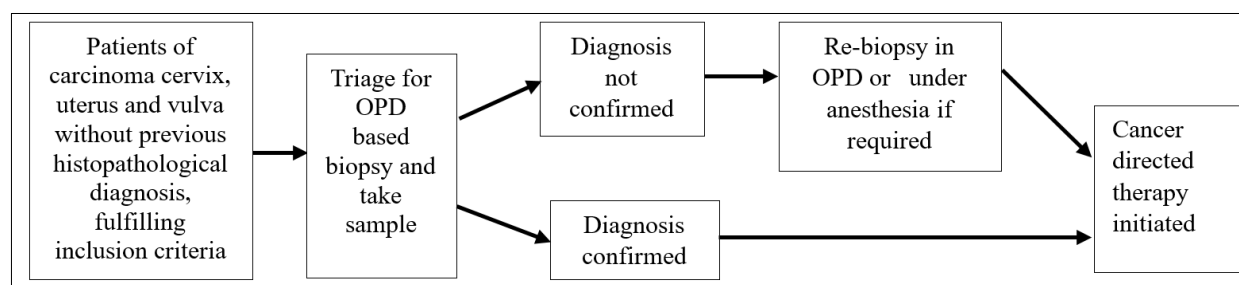


Figure 1: Work flow of the patient diagnosis and treatment initiation. The time to treatment initiation (rectangle box) where radiotherapy is the primary treatment, was not affected by this strategy, owing to waiting lists for treatment.

RESULTS

A total of 145 patients who fulfilled the inclusion criteria for the study, between March 2022 to December 2024 were

included for the final analysis. The average age of the patients was 54 years; 20 percent patients were from Tier 1 cities while 80 percent were from Tier 3 cities of Uttar Pradesh. The distribution of type of cancers and the result

of the biopsy in terms of re-biopsy rate is depicted in Tables 1 and 2.

Table 1: Primary cancer site-wise distribution of biopsies taken.

Types of cancers	Distribution (n=155)
Cervical precancer	6
Cervical cancer	125 (9 early stage, 84 locally advanced, 9 advanced stage, 23 vaginal vault or cervical stump)
Vaginal carcinoma	8
Endometrial carcinoma	9
Vulvar carcinoma	7

Table 2: Status of re-biopsies.

Result of re-biopsies	Status
Total re-biopsies	9 (6 in OPD and 3 in OT under local anesthesia/sedation))
Diagnosis confirmed after re-biopsy	7 (5 in OPD and 2 in OT under anesthesia)
Diagnosis not confirmed despite re-biopsy under sedation/anesthesia	2

Hysteroscopy guided biopsy was necessary in all women with endometrial hyperplasia on imaging but the diagnosis did not change after surgery in any of these women except 1 (total n=15).

The most common adverse event was post-biopsy bleeding after cervical or vulval biopsy, that were managed in the OPD itself by antiseptic-soaked linen tamponade and oral hemostatic followed by 15 to 30 minutes observation. Where heavy bleeding was expected or observed, parenteral tranexamic acid was given. Requirement of day-care/overnight admission was only for 1 patient of vulval biopsy. All patients were given oral anti-inflammatory medication for pain and where necessary, tramadol and antiemetics were given. There were no serious adverse events observed. The following precautions were taken before all procedures: anti-inflammatory medication before or after procedure, where indicated, use of sterile/disposable instruments without re-use in the same day, universal infection control measures, vaginal tamponade and oral/parenteral tranexamic acid. Antibiotics were given in patients with vaginal or cervical infections and procedures were deferred.

It was observed that larger size lesions i.e. more than 2 cm were readily biopsied while colposcopy/vulvoscopy were utilized free of cost in case of smaller lesions that were difficult to visualize otherwise. Pyometra drainage was also performed for the cervical cancer patients during

biopsy in the OPD itself (n=5), this procedure has a separate package rate under the scheme.

Accuracy

The accuracy of OPD based biopsies was 94.2 percent, while the accuracy of OT based biopsies was 90 percent indicating that stenosed cervix in post-menopausal women is difficult to dilate and biopsy accurately. All three of these cases had associated cervicovaginal infections that required antibiotics for 7 to 14 days.

Costs

The one-time capital investment cost for instruments was 35-40 thousand Indian rupees equivalent to 4- 5 hundred US Dollars. The minimum shelf life of these instrument with proper maintenance is 10 years. The health insurance package costs were taken from the PM JAY rates available in the hospital, including both lowest (INR 3000) and highest (INR 7000). The OPD based biopsy strategy included the cost of registration, cost of biopsy reporting, while the procedure charge was included in the OPD registration charge.

Cost-utility

The incremental cost effectiveness ratio favored the OPD based biopsies as depicted in the cost-effective frontier, with no incremental gain in QALY, the cost effectiveness plane is depicted in Figure 2. Strategy 1 lowest cost or tier3 package, strategy 2 highest cost or tier1 city package and the OPD based biopsy strategy and are depicted in Figure 3. The PM JAY package strategies were rejected as they occupied quadrant 1. The OPD based strategy is closest to the X axis indicating this intervention as equally effective and least costly.

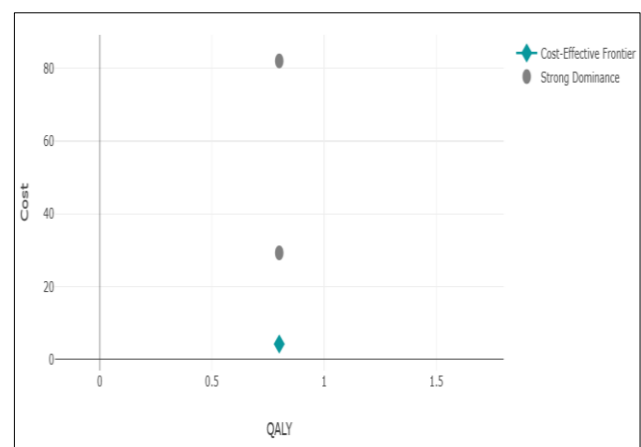


Figure 2: The cost effectiveness plane depicting OPD biopsies as the cost-effective frontier with a strong dominance in effect of all procedures while least cost of the OPD procedures at 4.2 USD.

lowest PMJAY package (cervix/vulva endometrium)	0.8	29.3	Rejected
highest PMJAY package cost (cervix/vulva endometrium)	0.8	82	Rejected
OPD based biopsy rate	0.8	4.2	Accepted

Iteration 2

Strategy ▾	QALY ▾	Cost ▾	ICER ▾	Status ▾
OPD based biopsy rate	0.8	4.2	-	Accepted

Figure 3: A comparative depiction of the costs of the three strategies in US dollars while considering same impact on QALY which was considered as 0.8 for early to locally advanced stages of cervical cancer and endometrial cancers, which constituted majority of the study population. The OPD based strategy was acceptable.

DISCUSSION

Most common gynecological cancers afflicting women in India and Southeast Asia are the cancer of uterine cervix, ovary and endometrium, with patients presenting in the advanced stages in their initial hospital visit. This was also observed in the cohort of patients in our study. Advanced cervical and uterine cancers were biopsied in the OPD itself while patients underwent office hysteroscopy and biopsy for diagnosing endometrial hyperplasia and early-stage endometrial cancer. It is necessary to triage and personalize diagnostic procedures for endometrial precancer and cancer to reduce number of hospital visits and obtain an early diagnosis. Performing office procedures can be offered among such women. It is recommended to biopsy endometrial cavity after visualization to avoid missing early invasive disease. This can be personalized based on clinical examination imaging and symptoms of patients.¹⁰

Cervical biopsy yielded an accuracy of 94 percent for invasive disease in majority of the patients, while it was lower for smaller lesions and endocervical lesions in postmenopausal women. The audit by Bonow et al on accuracy of colposcopic diagnosis of high-grade lesions confirms that higher grade lesions are easily diagnosed on visible examination, thus biopsies of invasive lesions are also easier to perform.¹¹

Cost of surgical services both outpatient and inpatient are although significant yet it is lower than the cumulative cost of chemotherapy or radiation. However, if the diagnostic procedures are considered, they are an imperative to initiate any form of therapy. Thus, it is of critical value to have data on the cost of delivering surgical services at the level of primary, secondary and tertiary care hospitals for evidence-based policy-making, price-setting for surgical care and planning to strengthen the availability of high quality and cost-effective surgery care. The cost of OPD based procedures at 4.1 USD in this study corroborates with the findings of Singh et al in their phase II of costing of health services in India study.¹² Considering that our

study is based in a tertiary care hospital, innovation and skilling in health care service delivery can not only decrease costs but also make room for budgetary re-allocation for newer surgical procedures, such as intraperitoneal chemotherapy, or for certain targeted therapy.

Introduction of this scheme has also shown a shift of increased healthcare access for treatment in private sector by the economically disadvantaged group, where the scheme is more utilized.¹³ However, this does not necessarily interpret into optimum utilization of the designated 5 lakh rupees, where the entire treatment of cancer may not be available under one roof. Thus, decision making for optimum budget utilization must be judicious at both the individual clinician and the multidisciplinary group level, for chronic diseases such as cancer. Prinja et al in their assessment of financial toxicity of cancer treatment in India describe a mean direct out of pocket (OOP) expenditure of ₹8,053 (US\$ 101) per out-patient consultation and ₹39,085 (US\$ 492) per episode of hospitalization, out of which 36% was contributed by diagnostics alone.¹⁴ The strategy of outpatient biopsies can provide significant reduction in such expenditures. They also highlighted greater expenditures in the private sector, thus reallocation and re-framing of the packages, with fewer low budget packages for diagnostic procedures may help direct funds towards more complex treatments and procedures that provide incremental health gains to such patients in the long run, irrespective of which sector hospital is accessed. The study on health package policy interventions and modifications demonstrated a significant positive impact of health package revisions on the scheme utilization.¹⁵ Our study aims to provide significant information for further health package revisions and creation of new cancer specific packages.

Delays in healthcare access and diagnosis significantly affect the prognosis. Public health insurance programs and the availability of public hospitals with adequate diagnostic and therapeutic facilities have frequently

proven their effectiveness in mitigating delays in cancer treatment initiation.¹⁶

A significant contributor to success of office procedures would be up-skilling of healthcare providers and clinicians who treat patients with cancer. The accuracy rate of procedures was dependent on the experience and expertise of those sampling and reporting the specimens in our study.^{17,18} The procedures in this study were performed by experienced specialists and trainees who had undergone supervised training for at least a year.

Cost-effectiveness versus cost-utility

This study compares the costs and effectiveness of an intervention done in two different settings, while the procedure is similar in both the settings. The outcome measure of QALY has been selected since a diagnostic procedure is being studied and the health outcome gain is similar in both settings. QALY was also considered as a more suitable outcome for this study since multiple disease sub-sites, such as cervix, uterus and vulva, were being studied where treatment and survival outcomes are varied, therefore the quality of life after treatment completion was considered generalizable and acceptable disease subsites.¹⁹

Limitations

This is a single center study which is a tertiary care hospital for treatment of cancer, thus the findings of the study may not be exactly replicable to settings different from this. However, the description of instrumentation and procedures can facilitate the learning and replication by other lower resource set-ups. The study also underscores the value of detailed patient evaluation during out-patient visits, which saves both costs and time and often good clinical evaluation may significantly reduce requirement of unnecessary ineffective imaging.²⁰

CONCLUSION

This analysis concludes that OPD based biopsies or office procedures are very cost-effective and can significantly and positively impact out-of-pocket expenditure for patients seeking cancer treatments, while saving the costs in the insurance scheme packages.

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