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Original Article / Оригинални рад

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Intraoperative digital specimen radiography in the treatment of nonpalpable breast lesions

Интраоперативна дигитална радиографија узорка у лечењу непалпабилних промена дојки

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SUMMARY

Introduction/Objective About a third of the breast lesions on mammography are clinically occult. The goals of the surgery are to locate, remove and verify the presence of them in the removed breast tissue. Specimen mammography was an official procedure for the latter while intraoperative digital specimen radiography was introduced recently.

The aim of this study was to evaluate the use of intraoperative digital specimen radiography (IDSR) versus standard specimen mammography (SSM) and the possible benefits regarding the duration of the procedures and operating room occupancy, availability of digital mammography for additional number of patients, surgeon productivity, and the quality of performed services.

Methods A retrospective chart review of 109 patients who underwent IDSR for nonpalpable breast lesions was performed between January 2014 and June 2016. We compared the difference in the duration of IDSR versus SSM procedure. We also observed the number of re-excisions and evaluated timesaving in the operating room workflow.

Results The average duration of surgery in the IDSR group of patients was 51 minutes compared to 64 minutes in the SSM group. Every IDSR procedure saved 13 minutes over the standard SSM. That would allow another 28 procedures in the same time frame, with the same quality of service compared with SSM. In that way we increased productivity by 27.5%. Additional operation/surgery was needed for histologically involved surgical margins in three cases (2.75%).

Conclusion The use of new technology resulted in the rationalization of the operative room workflow and gives a better productivity. More savings were obtained through the increase of digital mammography capacity for diagnostics, decreases the anesthetic time, and allow better management of human resources. The number of "true" re-excisions, involving additional surgery remained similar after introducing IDSR.

Keywords: breast tumors, nonpalpable, localization; specimen radiography

САЖЕТАК

Увод/Циљ Трећина мамографским прегледом нађених промена у дојци је непалпабилна. Циљ хируршког лечења је да локализује, уклони и потврди присуство промене у одстрањеном ткиву. Мамографија узорка је била стандардна метода за потврду, а интраоперативна дигитална мамографија је уведена недавно.

Циљ рада је био да се одреди евентуални бенефит интароперативне дигиталне радиографије узорка (ИДРУ) у односу на стандардну мамографију узорка (СМУ), у трајању операције (заузетости операционе сале), ослобађања капацитета дигиталног мамографа за додатни број прегледа, у продуктивности и квалитету пружене услуге.

Методе ретроспективно је анализирано 109 картона болесника са ИДРУ од јануара 2014. до јуна 2016. Време трајања операције са ИДРУ је упоређивано са временом трајања операције код СМУ. Посматран је број реексцизија и процењена је уштеда у времену рада операционе сале.

Резултати Просечно време трајања операције је 51 минута у ИДРУ групи у односу на 64 минута код СМУ. Свака процедура ИДРУ је донела уштеду у времену од 13 минута у односу на СМУ. Таква уштеда би дозволила извођење још 28 додатних процедура у односу на СМУ у истом временском оквиру са истим квалитетом услуге. То значи повећање продуктивности за 27,5%. Друга хирургшка интервенција због позитивних ресекционих ивица је била потребна у три случаја (2,75%)

Закључак увођењем нове технологије постигнута је рационализација у раду операционе сале и повећана је продуктивност. Неоспорна је и уштеда због ослобађања капацитета дигиталног мамографа за дијагностичке потребе. Скраћење времена трајања анестезије доноси материјалне уштеде и рационализацију у управљању. Број реексцизија у другом акту је практично непромењен након увођења ИДРУ.

Кључне речи: тумори дојке, непалпабилни, локализација; спесимен радиографија

INTRODUCTION

The treatment of breast tumors has significantly advanced thanks to the new technologies and new drugs, that have led to better understanding of the nature of the disease. Intraoperative digital specimen radiograph represent such a technology. It shortened the operative time, increase the

productivity and decrease the work costs. A number of scientific papers report on the ways to rationalize the work of operating room [1, 2, 3].

Screening for breast cancer reveals an increased rate of nonpalpable changes which require the use of various techniques for their localization followed by histological verification [4, 5]. The use of percutaneous core biopsy and vacuum assisted biopsy (VAB) solve diagnostics for a number of lesions without the need for surgery [6, 7, 8]. However, the malignancies confirmed by these biopsies, intermediary histological findings or suspicious malignancies are not suitable for core biopsies because of their localization, size or other contraindications should be managed by open biopsy. Localization of such lesions is often performed by a hook-wire [9], radiotracer (radioguided occult lesion localization - ROLL) [10, 11], dye or metallic clips placed at the site of percutaneous biopsy or can be done by intraoperative ultrasound localization [12, 13]. These markers help the surgeon to localize and excise the lesion precisely. Because those lesions are often nonpalpable and/or invisible even in the excised tissue, it is necessary to confirm that they have been excised completely [11, 14, 15]. This can be achieved by standard specimen mammography (SSM) or intraoperative digital specimen radiography (IDSR) [16, 17].

The aim of this study was to evaluate the use of intraoperative digital specimen radiography (IDSR), which replaced the previous standard specimen mammography (SSM) on December 2013th. We evaluate the possible benefits regarding the duration of surgery and operating room occupancy, availability of digital mammography for additional number of patients, surgeon productivity, and the quality of performed services. This method allows surgeon and/or radiologist to immediately interpret the specimen in the operating room.

METHODS

A retrospective study of patient charts and operative protocols gave us the data for 109 patients from 2014 to June 2016. Around a half of the patients underwent preoperative percutaneous biopsy, the rest was proven by frozen section during their surgery. In case of histologically confirmed or suspicious lesions for infiltrative carcinoma visible on ultrasonography, lesion localization was performed primarily by radiotracer, which allows sentinel node identification, or we used wire localization with para-areoalar injection of the radiotracer. Otherwise, the sentinel node would have to be examined in a separate procedure. The third method is the use of ultrasound pre- and intraoperatively for lesion localization. The preoperative part is often done by a radiologist by marking the lesion over the skin, intraoperatively ultrasound is available to the surgeons. After lesion localization all patients underwent breast conserving surgery (BCS) with or without sentinel node (SN) identification, and axillary dissection for metastases.

The duration of the procedure for the IDSR group were obtained from the operative protocols. Since the SSM procedure differ from IDSR only in the time needed for transportation, the radiological technicians to obtain a specimen mammogram and radiologist to interpret the same, we simply

calculated and added that time to the results we get for the IDSR group (Table 1). Those measurements were done three times by a stopwatch and the average time was 6, 5 and 3 minutes. We never considered the possibility of mammogram examination of a patient being in progress, which would prolong every procedure for up to 20 minutes.

Table 1. Sequence of actions for SSM and IDSM procedure.

SSM	Duration/ min.	IDSM	Duration/ min
1. The surgeon excise the localized lesion and mark it for better orientation			
2. Transport the specimen to the Center for imaging diagnostics	6	2.No action	0
3.The technician takes images of the specimen	5	3. The assisting scrub nurse takes image of the specimen in the operating room. The surgeon see it on the monitor. The radiologist can read the image simultaneously on his monitor; consultation is upon surgeon decision.	1
4.The radiologist reviews the image and communicates the results to the surgeon	3	4. No action	0
5. "Frozen section" analysis of excised margins			
6. Re-excision of the tumor bed			
7. Identification of sentinel node and axillary dissection if SN is positive			
8. The end of the procedures.			

We divided all patients from the IDSR to subgroups in order to precisely evaluate the time needed for tumor excision, those who had re-excision, SN identification, or both (re-excision + SN) and those who underwent axillary dissection.

In addition, we estimated the total number of re-excisions indicated by the surgeon and radiologist on the ground of IDSR, or other reasons (visual or palpatory findings in the tumor bed), or by the pathologist, frozen section analysis of the resected margins.

We estimated the total number of additional surgery for the group too. The productivity was assessed in relation to the predicted timesaving with the use of IDSR.

RESULTS

The localization procedure were pre- and intraoperative ultrasound in 66 (60.5%), "hook-wire" in 29 (26.6%) and ROLL in 14 (12.8%) cases.

Out of 109 lesion localizations, 52 (47.7%) of the patients underwent preoperative percutaneous biopsy; the rest 57 (52.3%) was proven by frozen section during their surgery.

29 (26.6%) patients were verified to have benign lesions while 30(27.5%) had infiltrating carcinoma, 28 (25.7%) "in situ" and 22 (20.2%) the combination of the two.

There were discrepancies between the histological findings on "core" biopsy and open surgery in 9 (8.25%) cases (Table 2).

The average diameter of the invasive tumor was 12.8mm (ranging 4-30), for in situ tumors 13mm (ranging 0.2-35), and the combination of the two 12.5mm (ranging 1.5-30).

Table 2. Discrepancies between histological findings on percutaneous biopsy and open surgery.

	Percutaneos biopsy	Surgical biopsy
1.	Fibrosclerosis	Ductal CIS, G2, 3,5mm
2.	Papillary tumor	Papillary CIS, G1,10mm
3.	Papillary tumor	CIS, G?, 8mm
4.	DCIS,G3	Ductal microinvasive, G3, 3mm
5.	CDI,G2, DCIS,G2	DCIS,G2
6.	CDI,G2, DCIS,G2, 4mm	ADH
7.	DCIS,G2,11mm	No tumor
8-9.	CDI,G2, >40mm	No tumor after neoadjuvant treatment

CIS-Carcinoma in situ , G- Grade of the tumor , CDI-Carcinoma ductale invasivum, ADH- Atypical ductal hyperplasia

The average duration of surgery in the IDSR group of patients was 51 minutes compared to 64 minutes in the SSM group. Every IDSR procedure saved 13 minutes over the standard SSM. That would allow another 28 procedures in the same time frame with the same quality of service compared with SSM. In that way we increased productivity by 27.5%.

The average 51 minutes would be prolonged another 11 minutes, if re-excision is needed. In case of SN identification the average time is 66 minutes, a combination of the two would give 83 minutes, up to 97 minutes for axillary dissection.

Table 3. Number of additional surgery indicated by involved surgical margins

	Primary procedure „frozen section“	Additional (second) surgery	3 or > more procedures
1.	Free margin (2mm) on frozen section	CDI, G2 on the margin	-
2.	No tumor on the margin	CLI, LCIS on the margin	LCIS on the margin solved by mastectomy
3.	No tumor on the margin	DCIS, G2 on the margin	-

CDI-Carcinoma ductale invasivum , CLI-Carcinoma lobulare invasivum, LCIS-Ca lobulare in situ, DCIS-Ca ductale in situ

The number of re-excisions during the procedure was 33 (30,3%). Additional operation/surgery was needed for histologically involved surgical margins in three cases (2,75%). In one case after the second surgery and LCIS on the margin, mastectomy was performed (Table 3).

DISCUSSION

It must be said that in SSM procedure potential errors regarding the identification, orientation, and transportation of the excised specimen are possible; this can lead to misinterpretation of resected margins by the pathologist. Compression of the specimen during mammography imaging can cause overlapping of the margins, which can result in false positive or negative excised margins. The use of IDSR allows for an immediate evaluation of the specimen, confirmation of the complete removal of targeted tissue, and the assessment of excised margins. Our study confirmed that the procedure was shorter for 13 minutes with IDSR compared to SSM. Similar findings were reported in Kaufman et al. study [18]. Other studies do not state similar results [19]. Our results showed that preoperative percutaneous biopsy and histological verification of an occult lesion did not shortened the duration of the procedure significantly. It can be explained with practice of frozen section analysis of surgical margins in all patients beside the IDSR.

Every IDSR procedure saved 13 minutes over the standard SSM. That would allow another 28 procedures in the same time frame, with the same quality of service compared with SSM. In that way we increased productivity by 27.5%.

We expect more benefit in the future knowing the impact to the learning curve and engagement of all surgeons in IDSR procedure.

Different studies report positive resection margins up to 40% of the patients treated with breast conserving surgery [20, 21]. This leeds to additional surgery, adverse effects on cosmetics, psychological distress and higher costs.

According to other authors the percentage of re-excisions performed in the course of operation is comparable to ours (30%) [17, 22] or lower [18, 23]. IDSR optimize the surgical procedure, because the surgeon, radiologist and pathologist have a real-time information about the positive resection margins [22]. It is now possible to exchange opinions directly with no additional time consumption. We had tree re-operations (2.75%) in our study, McCormick et al. 12%, after two-view specimen mammography they reduced that rate to 5% [23]. The future goal is to avoid additional operations and increase productivity as much as possible.

CONCLUSION

The use of new technology resulted in the rationalization of the operative room workflow and gives a better productivity. More savings were obtained through the increase of digital mammography capacity for diagnostics, decreases the anesthetic time, and allow better management of human resources. The use of this method slightly increased the number of re-excisions during the primary operation. The number of "true" re-excisions, involving additional surgery remained similar after introducing IDSR.

The use of IDSR in everyday practical work has made possible for surgical team to make and interpret specimen radiograms and make immediate surgical decisions based on these images.

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