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Charcoal Localization for Surgical Resection of Non-Palpable Suspicious Breast Lesions.

A promising method for communities of low resources. A prospective observational effectiveness study.

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Rezumat

Marcajul cu cărbune a leziunilor mamare infraclinice suspecte - o metodă promițătoare pentru comunitățile cu resurse limitate Un studiu prospectiv observațional.

Context: Frecvența detectării cancerului mamar infraclinic a crescut odată cu implementarea programelor naționale de screening. Mai mult, dimensiunile tumorilor detectate au scăzut în ultimii ani, impunând, într-o proporție semnificativă din cazuri, o localizare imagistică cât mai precisă în vederea exciziei chirurgicale. Deşi localizarea prin intermediul harponului a fost metoda cea mai frecvent utilizată timp de mulți ani, acest sistem prezintă o serie de dezavantaje care îi limitează aplicarea. Localizarea radioghidată a leziunilor oculte (ROLL) este în prezent metoda standard de marcaj. Cu toate acestea, nu este disponibilă în majoritatea comunităților cu resurse limitate. Acest fapt încurajează utilizarea cărbunelui, o metodă simplă şi ieftină de marcare a leziunilor mamare suspecte infraclinice.
Metode: Acest studiu prospectiv a inclus 34 de paciente care au prezentat leziuni mamare suspecte, nepalpabile (BIRADS 4 sau 5). Tuturor pacientelor li s-au injectat sub ghidaj ecografic 1-3 ml granule de cărbune în suspensie apoasă 3% la marginea superficială a leziunii suspecte şi pe traseul dintre leziune şi punctul de intrare a acului în piele care va reprezenta locul viitoarei incizii. Această metodă a fost efectuată la majoritatea pacienților cu o zi înainte de operație. Totuşi, în 2 cazuri, excizia chirurgicală a fost

practicată după 6 zile de la localizare.
Rezultate: Au fost analizați 34 de pacienți cu un total de 36 de leziuni. Vârsta medie a fost de 43 de ani. Diametrul mediu al leziunilor a fost de 10,9 mm. Din 36 de leziuni gardul BIRADS a avut următoarea distribuție: 10 leziuni (4a), 12 leziuni (4b), 8 leziuni (4c) şi 6 leziuni (5). Investigațiile postoperatorii au evidențiat 16 leziuni maligne şi 20 leziuni benigne. Toate leziunile benigne au fost tratate prin excizie locală largă; Toate cele 14 leziuni BIRADS 4a s-au dovedit a fi benigne. Şaisprezece leziuni maligne au fost tratate după cum urmează: pentru nouă paciente s-a practicat chirurgia de conservare a sânului, pentru cinci pacienți s-a practicat mastectomie radicală modificată (trei pacienți au avut antecedente de mastectomie radicală modificată, un pacient a prezentat IDC multicentric şi în cazul unui pacient marginile de siguranță obținute în urma tratamentului conservator prezentau invazie tumorală), iar în cazul unui pacient s-a practicat mastectomie cu prezervarea mamelonului şi reconstrucție imediată a sânului prin lambou din marele dorsal. În acest studiu nu a fost raportată nicio complicație.
Concluzie: Marcajul cu cărbune prezintă numeroase avantaje în localizarea chirurgicală a leziunilor mamare.

Cuvinte cheie: marcajul prin cărbune, leziuni mamare infraclinice, comunități cu resurse limitate, cancer mamar, chirurgie mamară

Abstract
Background: Breast cancer is more frequently detected as radiographic non-palpable lesions with the increased utilization of national screening programs. Moreover, the sizes of tumors detected have decreased in recent years, increasing the need for accurate image-directed localization for surgical excision in a significant portion of cases. Although Wire guided localization has been the most commonly used method for many years, inherent problems remain and limit its practice. Radio-guided occult lesion localization (ROLL) is currently the standard method of localization, however, it is unavailable in most low resource communities. This encourages us to use charcoal localization which is a simple and cheap method of surgical localization of non-palpable suspicious breast lesions.
Methods: This prospective study included 34 patients who presented with non-palpable suspicious breast lesions (BIRADS 4 or 5). All patients were injected 1-3 ml of sterilized 3% aqueous suspension of charcoal granules under the guidance of ultrasound at the superficial border of the suspicious lesion and the track between the lesion and the needle entry point in the skin which will occur at the future incision. This method was carried out in most patients one day before the operation, however, two patients underwent surgical excision after 6 days of localization without any interruption.
Results: Thirty-four patients had 36 Lesions. The median age was 43 years. The mean diameter of lesions was 10.9 mm. Of 36 lesions; the BIRADS as follow10 (4a), 12 (4b), 8 (4c), and 6 (5). Postoperative investigations revealed 16 malignant lesions and 20 benign lesions. All 20 benign lesions were managed by wide local excision; All 14 BIRADS 4a lesions were proved to be benign. Sixteen malignant lesions were managed as the following; nine patients had breast-conserving surgery, five patients had modified radical mastectomy (three patients had past history of modified radical mastectomy, one patient had Multicentric IDC and one patient had infiltrated safety margins on conservation), and one patient had Nipple Sparing Mastectomy with immediate breast reconstruction by Latissimus Dorsi Flap. There was no reaction or infection reported in our study.
Conclusion: Charcoal localization has many advantages and helps surgical localization.

Key words: Charcoal localization, non-palpable breast lesions, low resources communities, breast cancer, breast surgery

Introduction

Breast cancer is considered the commonest cancer among females. About 25% - 35% of breast cancers are non-palpable at the time of the diagnosis (1). With the increased utilization of national screening programs, breast cancer is more frequently detected as radiographic non-palpable lesions in up to 50 % of cases (2,3). Moreover, the sizes of tumors detected have decreased in recent years, increasing the need for the accurate image-directed localization for surgical excision in a significant portion of cases, because precise localization of non-palpable lesions is an essential step to guarantee cancer clearance without compromising cosmetic results (4). Various techniques have been tried for accurate localization of non-palpable breast lesions; each with some advantages, risks and disadvantages. Wire guided localization (WGL) was the standard and the most commonly used localization method for non-palpable breast cancers during the 1990s in the absence of better alternatives (5), however this method is far from ideal and it has several disadvantages e.g., scheduling conflicts between the surgeon and the radiologist can occur, resulting from the need to coordinate multiple procedures on the same day list with different teams. There is an inability to use wire localization for the first start time in the morning without a significant delay in the operating room (6). In addition, the procedure necessitates surgical excision within very short interval after wire placement (7). The physical presence of a wire within the operative field can result in a more complicated incision and make the procedure of surgical excision with clear margins technically difficult. (8,9) There are many serious problems which may be encountered e.g., wire displacement, difficult re-positioning, and sometimes interference with the surgical approach itself. The wire may become displaced, migrate or be transected especially during mobilization of the patient, repositioning can be complicated by bruised tissue within the previously punctured tumor site (10). Wire placement is technically challenging with significant difficulty, especially in dense breast tissue. The relatively high cost of WGL for tumor localization compared to other techniques has proven to be prohibitively expensive for its implementation in many developing countries (7,11,12). Radio-guided occult lesion localization (ROLL) or radioactive seed localization (RSL) is another technique utilizing a radiopharmaceutical tracer which is injected in the lesion and which is commonly used for lymphatic mapping and sentinel node biopsies. In the same surgical procedure, the tracer can be used to localize the primary tumor guided by a gamma probe.

Based on the literature, compared to conventional WGL, the ROLL technique seems to be faster, more accurate, more comfortable, and it provides a better cosmetic result and higher percentage of tumor free margins in the case of cancer patients (13,14) However, this method is unavailable in most low resource communities, to date there is no agreement about the most appropriate or standard method of surgical localization. This encouraged us to use charcoal aqueous suspension under ultrasound guidance (15). The aim of this study was the evaluation of the effectiveness and outcome of charcoal localization for surgical resection of non-palpable suspicious breast lesions in communities of low resources (15).

Patients and Methods

This is a prospective single cohort observational effectiveness study. It was carried out between July 2015 and May 2018, at the oncology center - Mansoura University (OCMU), Egypt. The design of this study was approved by the Institutional Research Board with written informed consents obtained from all patients before enrollment.

The Sample Target and Inclusion Criteria

All patients enrolled in this study were diagnosed with non-palpable suspicious breast lesion(s) either BIRADS 4 or 5 by breast ultra-

sound with or without mammography according to the age of patients. These lesions were non palpable so we tried to take a US guided biopsy, but it was either difficult to take a biopsy, insufficient radiologically guided biopsy or recommendation of pathologist for open biopsy for confirmation. Sometimes we were met with a refusal of the patient to undergo a radiological needle guided biopsy and the patient's preference for an open excisional biopsy. The exclusion criteria were women who had breast lesions BIRADS 1, 2 and 3 and patients who had a known history of drug hypersensitivity as we could not be sure about the reaction after charcoal injection, although the charcoal is inert.

Localization Technique

We used a 20 ml syringe with 20 gauge needle to prevent blockage by charcoal particles and during the procedure. The assistant nurse kept shaking the charcoal bottle during the procedure to prevent settling of charcoal granules. Sterilized solution of 3% aqueous suspension of activated charcoal granules was used. This activated charcoal was prepared from a local medical specialized supply store and used as a sterilized solution of 3% charcoal suspension dissolved in saline 0.9%. Actually this technique is very cheap in comparison with the other methods e.g., wire localization, also this concentration of aqueous suspension of activated charcoal was chosen as this is used in literature and permissible with no hazards for patients as it is injected locally

After identification of the non-palpable suspicious breast lesion by the radiologist using a real time ultrasound and injection of local anesthesia, 1-3 ml of sterilized 3% aqueous suspension of activated charcoal granules was slowly injected under ultrasound guidance at the superficial margin of the suspicious lesion (*Fig. 1*) & forming a track between the suspicious lesion and the point of needle entry in the skin (*Fig. 2*).

The amount of injection depends on the number and depth of suspicious lesion(s) which should be sufficient to make an easily intraoperative identifiable track. This was guided by a subjective judgment of the breast surgeon who attended with the radiologist while making charcoal marking of the lesion. The point of needle entry in the skin after charcoal localization acquired the black color of charcoal and remained fixed until surgery (*Fig. 3*).

This point was selected carefully and individually tailored according to the location and depth of the suspicious lesion, in order to

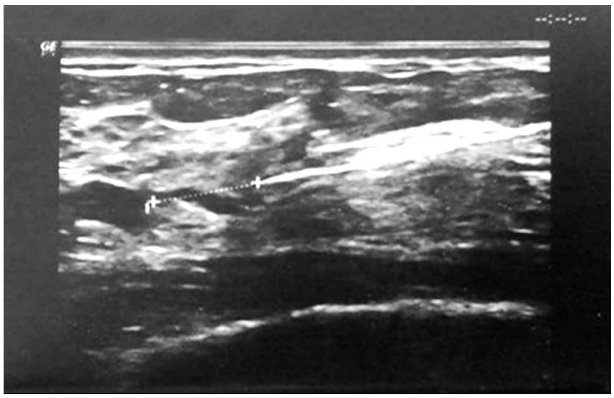

Figure 1. Ultrasound guided injection of charcoal at the superficial margin of suspicious lesion BIRADS 4a measured 5.5X4 mm in patient aged 36 years with positive family history of breast cancer. Postoperative pathology revealed fibroadenosis

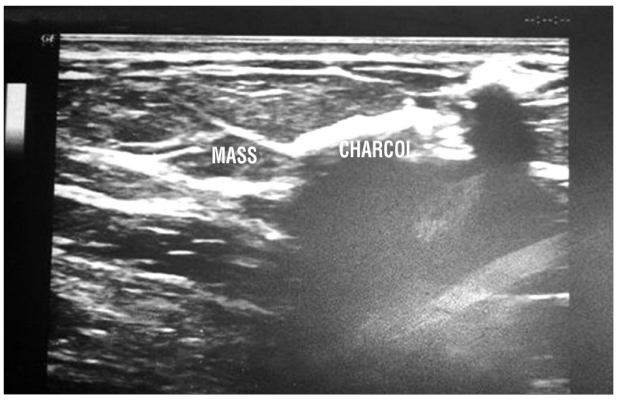

Figure 2. Ultrasound picture after injection of charcoal at the superficial margin of suspicious lesion BIRADS 4b measured 12.5X6 mm & forming a track between the suspicious lesion and the point of needle entry in the skin in patient aged 41 years with positive family history of breast cancer

Figure 3. The point of needle entry in the skin after charcoal localization acquired the black color of charcoal and remained fixed till surgery

Figure 4. The charcoal track was followed by dissection till reaching the superficial margin

facilitate the choice of skin incision and surgical procedure. To facilitate the intraoperative lesion identification, the following data were recorded in the localization report: depth of lesion, needle direction during injection, and the angle of insertion with the skin.

Surgical Resection

The charcoal track was followed by dissection until reaching the superficial margin (*Fig. 4*).

The breast tissue containing charcoal was excised all around with surgical safety cut at least 1cm grossly and this was guided also by frozen section if the margin was less than 1 cm (*Fig. 5*) around with surgical safety cut at least 1 cm (*Fig. 5*).

Figure 5. The breast tissue containing charcoal was excised all around with surgical safety cut at least 1cm, but in the depth it depended on the extension of the lesion that was described by preoperative ultrasound

In the depth it depended on the extension of the lesion that was described by preoperative ultrasound. After removal of the specimen, the remaining margins were landmarked (*Fig. 6*).

The sample was sent for intraoperative frozen section analysis. All patients with benign results or breast conserving surgery for malignant results were followed up by ultrasound at 6 months after surgery in order to detect any suspicious lesions at the site of resection, but cases diagnosed as breast cancer were managed as cases of breast cancer for adjuvant treatment and followed the follow-up protocol. Regarding the malignant cases diagnosed the axillary dissection was done for axillary lymph node clearance , this was done as axillary clearance tailored case by case either formal axillary dissection or sentinel lymph node dissection.

Figure 6. After removal of the specimen, the remaining margins were landmarked and send to intraoperative frozen section analysis

Results

This prospective study included 34 patients who presented with non-palpable suspicious breast lesion (BIRADS 4 or 5). This number of patients is limited because few patients present with an early non palpable lesion in our community, also, there are patients who cannot be diagnosed with guide biopsy. The median age was 43 years (range; 36 - 50). Ten patients presented with positive family history of breast cancer and three patients had past history of breast cancer and were treated with modified radical mastectomy within 2 years.

Two patients presented with bifocal lesions, so 34 patients had 36 lesions. Of the 36 lesions, 10 lesions were BIRADS 4a, 12 lesions were BIRADS 4b, 8 lesions were BIRADS 4c, and 6 lesions were BIRADS 5. The largest diameter of these lesions ranged between 4 - 15 mm (Mean 10.9 mm). Postoperative pathological results revealed 16 malignant lesions (*Fig. 7*) and 20 benign lesions; 15 Fibroadenosis with epitheliosis (*Fig. 8*), 3 Fibroadenomas, one fibroadenomatoid hyperplasia, and one sclerosis adenosis. All 20 benign lesions (in 19 patients) were managed by wide local excision. The pathologist did not report any more

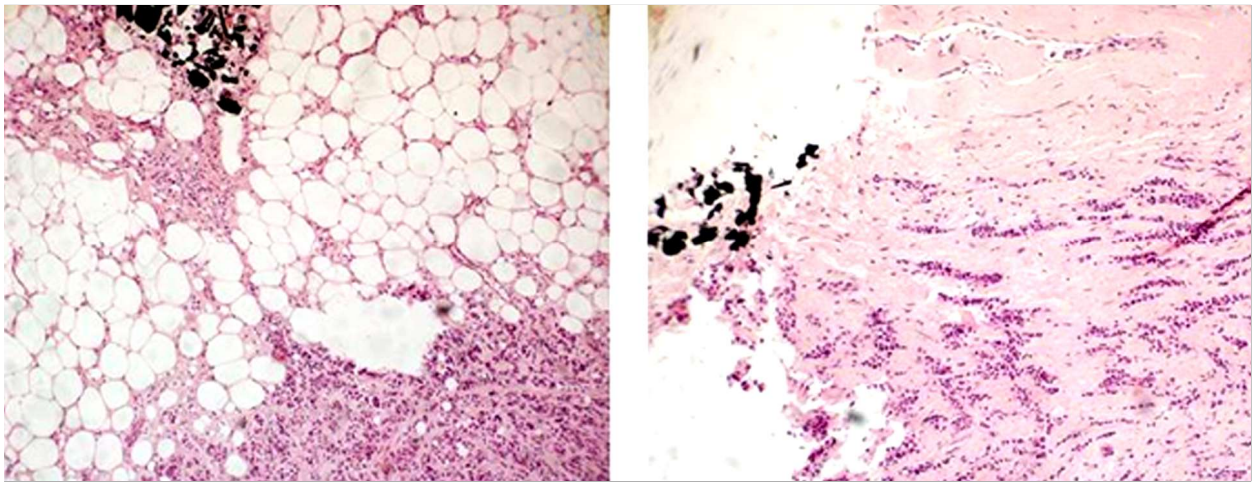

Figure 7. Malignant lesions with Charcoal localization

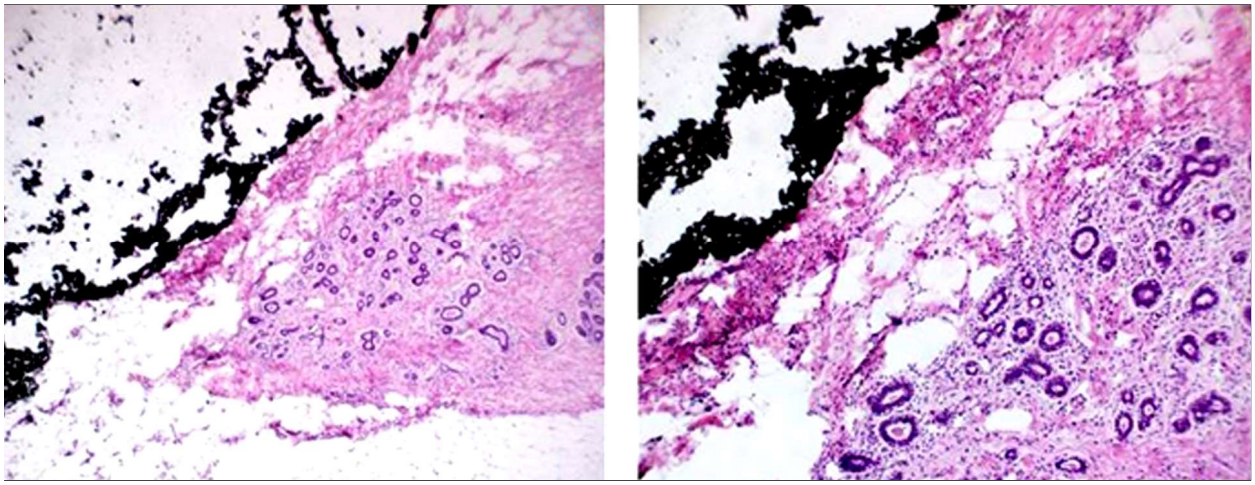

Figure 8. Fibroadenosis with epitheliosis with Charcoal localization. Charcoal staining did not interfere with histopathologic examination which could be carried out without any difficulties

difficulties due to the charcoal injection in the issue of histopathological assessment of the post excisional biopsy.

Sixteen malignant lesions (in 15 patients) were managed as follow: 9 patients underwent breast conserving surgery with free all surgical margins proved by both intraoperative frozen section analysis and postoperative paraffin section analysis, 5 patients underwent modified radical mastectomy (3 of them had past history of modified radical mastectomy for contralateral breast cancer, one patient had multicentric intraductal carcinoma and one patient had infiltrated safety margins on conservation), and one patient had Nipple Sparing Mastectomy (NSM) with immediate breast reconstruction by Latissimus Dorsi flap due to failure to achieve free safety margins in conservation (*Fig. 9*).

Localization was carried out in most

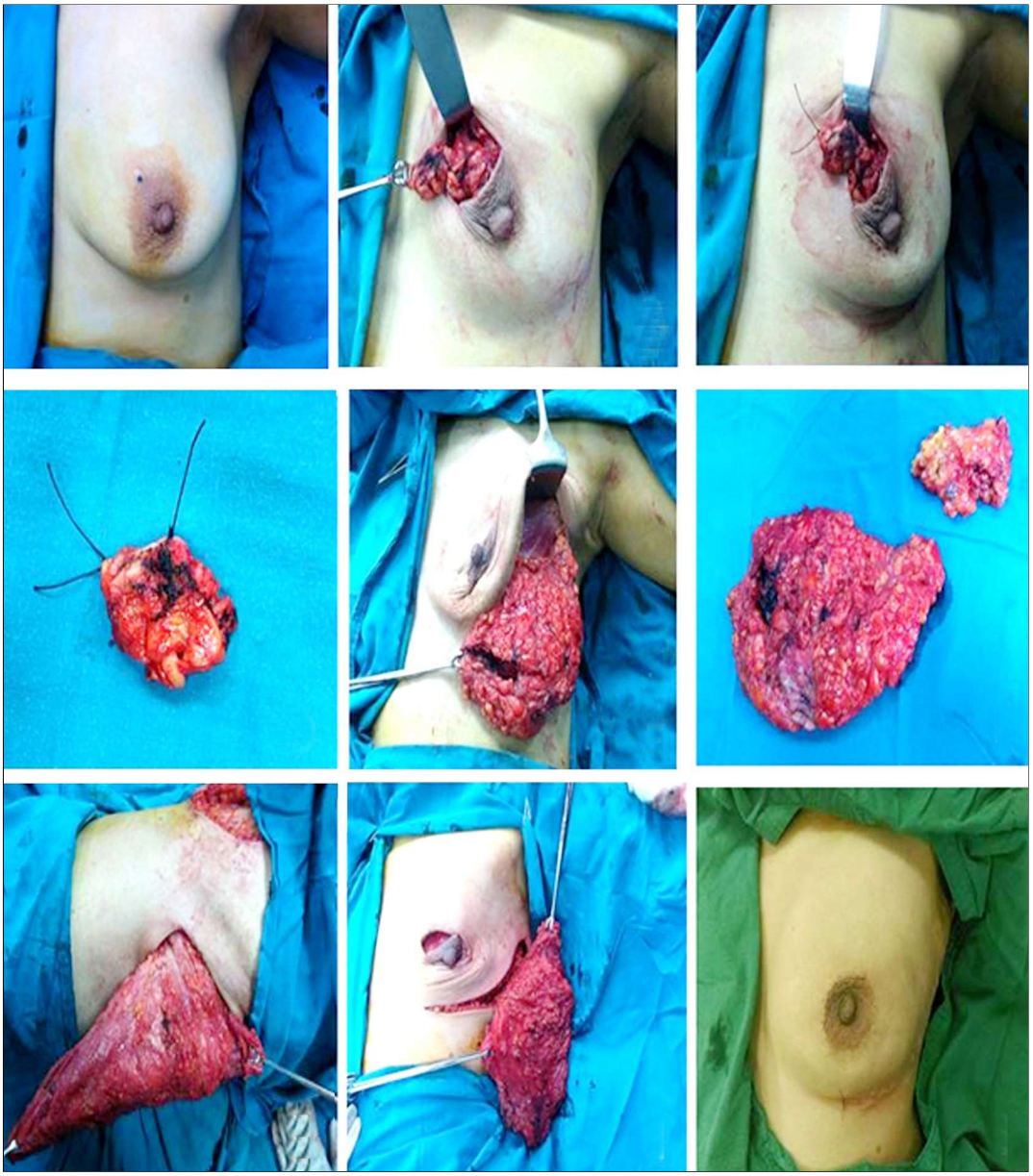

Figure 9. One patient had Nipple Sparing Mastectomy (NSM) with immediate breast reconstruction by Latissmus Dorsi flap, due to failure to achieve free safety margins in conservative

patients one day before operation, however, two patients underwent surgical excision after 6 days of localization without any interruption during surgery. Regarding the complication observed after using this technique, there was no reaction or wound infection reported in our study. Charcoal staining did not interfere with histopathological examination which could be carried out without any difficulties (*Figs. 7, 8*). Breast ultrasound follow-up of all patient at 6 months after surgery for benign results (19 patients) or breast conserving surgery for malignant results who were followed up as our usual protocol in such malignant cases (9 patients) did not detect any suspicious lesions or technique related complication such as granuloma or wound complication.

Discussion

Breast cancer is considered as the first malignant tumor affecting our females in Egypt, as in all over the world and also as improvement of the screening programs and awareness of the importance of these programs aiming for the early diagnosis of breast cancer in early stages for a better cure rate. Another challenge has evolved and that is how to deal with the impalpable suspicious breast lesions deserving tissue biopsy. Many techniques have been tried for preoperative localization of the non-clinically detected suspicions lesion depending on the availability of tools and experience of the doctors (16). Preoperative breast lesion localization techniques currently available are wire localization, carbon marking, radio-guided occult lesion localization (ROLL), radioactive seed localization (RSL), magnetic seed localization and non-radioactive radar localization, intraoperative ultrasound and preoperative skin tattoo localization (24). Nearly all these techniques relay on the cooperation of both surgeon and the radiology team. The most popular techniques include, wire localization, radioactive guided material seeding within the occult lesion, superficial skin mark, intraoperative US guidance, radioimmuno- guided location, magnetically detected lesions and dye detection such as blue dye or aqueous charcoal detection. With practice some disadvantages have occured for these techniques as in case of the wire localization the insertion of the wire should be within short time from surgery best immediately send the patient for O.R. after localization. This is hardly possible to arrange between both surgery team and radiology team for this task (6) many other complications have been noted such as displacement or broken wire (8). Another problem is the migration of the wire up to a position where it may lead to chest trauma (17,18). Also intraoperatively, the wire may be inside the tumor, removing it with little damage can cause thermal injury to the skin or limited skin incision (6). Also, there is an approximate 18% failure rate of the localization (19) regarding the other new techniques that depend on the radioactive materials, they imply more cost and experience. Moreover, this technique needs more communication between the radiologist, the nuclear medical team and the surgical one for injection of the radioactive material at the lesions and need special equipment (19) so some prefer to save this effort and cost for cases of preoperative biopsied lesion as a malignant one e.g., by cytology to benefit from doing radiolabeled tracing of the mass and sentinel lymph node in case the lesion may not be benign. Another technique is Magnetic guided tumor location which has drawbacks, as a surgeon you are guided to remove the tissue marked by the magnetic tracer which is not always that of the tumor and there is a need for more cooperation between the surgeon and radiologist for accurate detection of the tumor (3). In our country, as in other countries with limited income, all these high-cost techniques are not easily available and also should be saved for needed cases e.g., cases in need for sentinel lymph node biopsy so we started another applicable technique with less cost and good results. One of the most promising ones is the aqueous charcoal injection in the suspicious lesion with the excision of the marked areas and our result showed that the technique is better than other dye dependent

ones, e.g., blue dye as the blue dye will disperse in the tissue while this is accurately limited to the tumor. These results are in agreement with those of H.A. MOSS et al. 2002 (19) and very little better than those of ROSE et al. (21) as they recorded 9% missed lesion in the arm of charcoal localization. Also, we totally agree with the conclusion of the group that the advantages of charcoal localization include short course of training curve, least cost in comparison of its accurate result, patient comfort, less tissue removal with availability of good cosmosis with constant charcoal tract (21). Our results show no increased risk for wound infection as we used sterile solution but, due to the small sample, we advise repetition of the work with a larger sample.

Few studies in the literature denoted that there is some debate about the impairment of difficulty in the interpretation of histopathological assessment of lesions labeled with coal suspension, but in our study no difficulty was detected in this respect. Our results are in line with those of CAVALCANTI et al. (22) regarding the no detected change in the pathology of lesions.

Conclusion

Charcoal localization for surgical resection of non-palpable suspicious breast lesions have been found to have possible technical advantages such as being accurate and feasible technique which do not lead to any tissue dispersion (because activated charcoal is in particulate form and water insoluble, so it remains within the injected track). The stability of charcoal marking over time is one of its major advantages, therefore the tracing of the charcoal tattoo during surgery makes it easy to locate the lesion, which means that surgery can be planned over a period of many days. No reaction reported (charcoal is biologically inert). No need for particular equipment or instruments, along with low costs and no interference with histopathology. Our study has its limitations. We found that the maximum period that patient came for follow-up was only 6 months; also we enrolled a small sample size who underwent charcoal injection procedures, therefore, we do not have complete data for follow-up. Unfortunately, we could not add more cases. We need to confirm the results with a larger sample and longer period of follow-up.

Conflicts of Interests

The authors declared no potential conflicts of interest.

Funding

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Ethics Approval and Consent to Participate

The work was approved by the local ethical committee in our departmental ethical committee of our center - faculty of medicine before the start of the study and all patient had consented to be enrolled in the study.

Availability of Data and Materials

We agree about the all data and materials are available.

Authors' Contributions

Omar Farouk, Tamer Fady and Nazem Shams the planning of the research and design of study. Omar Farouk, Nazem Shams And Mohamed Ezzat operative work. Adel El-Badrawy Radiological assessment. Wagdi El-Kashef pathological assessment. Omar Farouk, Mohamed Ezzat and Tamer Fady draft writing. Nazem Shams, Omar Farouk and Ahmed finalizing writing and editing Omar Farouk, Ahmed Senbel and Mohamed Ezzat publishing.

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