

Sentinel node in breast cancer as an indicator of quality in medical care: Evaluation of statistics in Colombia

Mario Arturo González Mariño*

Department of Obstetrics and Gynecology, Faculty of Medicine, Universidad Nacional de Colombia, Bogotá D.C., Colombia

Abstract.

BACKGROUND: Sentinel lymph node biopsy in breast cancer is considered the standard of staging in cases of clinically negative lymph nodes. Its omission in favor of axillary dissection generates significant morbidity.

OBJECTIVE: To determine the total number of sentinel node biopsy procedures in breast cancer in Colombia from 2017 through 2020, model and analyze them as if they were performed only in stage I breast cancer patients, and integrate their results into the concepts of quality of medical care.

METHODS: Search in a database of the Ministry of Health and Social Protection of Colombia with sentinel lymph node biopsy codes, and filters of breast cancer and year. Their results are contrasted with the number of cases in stage I of breast cancer.

RESULTS: Breast cancer TNM staging was reported in 22154 cases, 3648 stage I. In the same time frame, the number of sentinel lymph node biopsies for breast cancer in Colombia was 1045, 28.64% of the total cases reported in stage I.

CONCLUSIONS: Colombia is far from complying with the standard indicator of sentinel lymph node biopsy. It is recommended to concentrate breast cancer cases in hospitals that provide the conditions for its performance.

Keywords: Breast, neoplasms, procedures and techniques utilization, axilla, lymph node excision

1. Introduction

Sentinel node biopsy in women with breast cancer and clinically negative lymph nodes is considered the standard of care for axillary staging, replacing axillary lymphadenectomy by providing information on lymph node metastatic involvement with minimal morbidity [6].

The safety of sentinel lymph node biopsy in patients with negative nodes was established in the NSABP B-32 trial, which showed no difference in overall survival

between patients undergoing axillary lymphadenectomy and those undergoing sentinel node biopsy [27]. In addition, this group has a lower incidence of lymphedema and arm/shoulder morbidity, complications associated with decreased quality of life, and increased costs [32].

Some studies have shown that there is a greater probability of being scheduled for sentinel node biopsy when surgeons specialize or focus on breast cancer [1,26,32,33]. The learning curve for sentinel node biopsy can vary; however, once the multidisciplinary team gains experience with the procedure, identification rates of over 95% are achieved [5]. These results have consolidated this procedure as the technique standard of care in women with breast cancer who meet the selection criteria [18].

Stage I of the anatomical classification of breast cancer by the American Joint Committee on Cancer

* Corresponding author: Mario Arturo González Mariño, KR 30 #45-03 - Campus: Universitario - Edificio: 471 - Piso: 1, Bogotá D.C., Colombia. Tel.: +57 1 4606061; E-mail: marioar90@hotmail.com, martgoma99@outlook.es. ORCID: <https://orcid.org/0000-0003-2970-336X>.

(AJCC) comprises stage IA with negative nodes and T1 tumor and IB, which is rarely used [25], with microscopic N1 involvement when the tumors are T0 and T1 [17]. Stage II also includes some patients with negative nodes in stages IIA and IIB and patients who have metastases to movable ipsilateral level I and II axillary lymph node(s) (cN1) [17]. The information available on the clinical stages of invasive breast cancer in Colombia groups them into only 4 states, without subdivisions [4]. Therefore, the proportion of patients with negative nodes cannot be determined in stage II. In stage IIIB (T4 N0 M0) or stage III (N1) patients with complete node response after neoadjuvant chemotherapy, sentinel lymph node biopsy was not recommended in Colombia during the years in which the information for this study was collected.

Given that stage I during the years evaluated, presumably is composed entirely of patients with negative nodes (IA) and thus with indication of sentinel node biopsy, it is taken as a reference in the quality evaluation model of breast cancer care in Colombia.

A high-quality cancer care delivery system should incorporate evidence into clinical practice, which involves developing Clinical Practice Guidelines, measuring quality, and improving clinician performance [15]. The Institute of Medicine of the National Academy of Sciences (USA) recommends the use of systematic guidelines based on the best available evidence for prevention, diagnosis, treatment, and palliative care. Therefore, once they are available for one subject of cancer care, it should be done following these guidelines [20].

2. Methods

A search was undertaken in the national database of the Individual Service Provision Registry (RIPS) of the Ministry of Health and Social Protection of Colombia with the sentinel lymph node biopsy codes with staining and radiolabeling and the filters of breast cancer and year. Their results were interpreted with the estimated proportion of their indication, making it equivalent to the stage I breast cancer, and analyzed in the context of their relationship with the quality of medical care. Because the RIPS database does not collect information on sentinel lymph node biopsy by stage groups, the diagnoses of stage I breast cancer were obtained from another source of information that reports the incidence, prevalence, and mortality of the most frequent cancers [4].

Table 1
Breast cancer in Colombia and the relationship between sentinel node biopsy and stage I in the time frame 2017–2020

Year	2017	2018	2019	2020
Breast cancer*	6348	4855	7047	6593
Breast cancer	5416	4503	6295	5940
Staging				
Stage I	611	904	1211	922
Sentinel node biopsy	22	187	430	406
%**	3.60	20.68	35.50	44.03

*Diagnosed in each year, ** $(\text{Sentinel node biopsy}/\text{Stage I}) \times 100$.

3. Results

In Colombia, breast cancer was diagnosed in 24843 cases from 2017 to 2020. Of these, TNM staging was reported in 22154 cases, 3648 in stage I. In the same time frame, the number of sentinel lymph node biopsies for breast cancer in Colombia was 1045, 28.64% of the total cases reported in stage I (Table 1).

4. Discussion

In patients with primary breast cancer and clinically negative nodes, axillary lymphadenectomy has been gradually abandoned. Several randomized studies compare axillary lymphadenectomy with sentinel lymph node biopsy [22], demonstrating lower morbidity and better quality of life with the last procedure due to lower risk of lymphedema, infection, nerve and vessel injury, or shoulder dysfunction [7], with no evidence of long-term adverse effects on survival [8]. Therefore, it is considered the turning point in axillary surgery [6]. These advantages are reflected in the meta-analysis results that support the preferential use of sentinel node biopsy. Routine axillary lymph node dissection does not provide any survival benefit compared with sentinel lymph node dissection in patients with clinically node-negative early-stage breast cancer [31]. Therefore, axillary lymphadenectomy for unaffected clinically and radiologically lymphatic nodes is no longer an acceptable practice in breast cancer [22]. In addition, it has a higher risk of morbidity [23].

The evaluation of costs between these two procedures varies among countries; however, the longer hospital stays and increased risk of lymphedema associated with axillary lymphadenectomy are consistent internationally [10].

Of a projected minimum number of sentinel node biopsy procedures in Colombia by making them

equivalent to patients with stage I, the number of sentinel node biopsies obtained constitutes less than one-third of the procedures expected in this stage (although the proportion has progressively increased over the years and in 2020 it was 44.03%). Therefore, despite the evidence in favor of sentinel node biopsy, it is not performed with the expected frequency, thus leading to numerous patients having more complications. This situation is not explained by the poverty of the patients because the health system pays for the procedure, but by administrative decisions that authorize breast interventions in places that are not adequately equipped instead of concentrating the cases in places with human and technological resources that allow the procedure. What happens seems to be caused by organizational limitations and, not by financial constrictions with many cancer patients treated in general hospitals, not in comprehensive cancer centers [13].

Oncology services in Colombia are mostly private (91.1%), and a minimum percentage are public services (7.9%) or mixed (1.0%) [24]. There are national norms regarding the obligation of all sectors (public, private, or mixed) to report the information of patients with breast cancer diagnoses to the corresponding health offices, from where they finally direct it to the Ministry of Health and Social Protection. However, the figures might not be an exact representation of the clinical practice because, despite the mandatory compliance norms and the existence of sanctions in case of non-compliance, it is passive epidemiological surveillance that therefore may have the usual limitations of this system [29].

A key element of quality monitoring is standardized measures of care. These may be used for self-assessment or external review of the quality of care [3], allowing centers to follow patients over time in a standardized manner, and easily recognize when attention is required to improve particular areas of health-care delivery [14]. The European Society of Breast Cancer Specialists (EUSOMA) includes the sentinel lymph node biopsy as a mandatory quality indicator in the surgery and quality of life section (avoidance of overtreatment). The indicator is described as the proportion of patients with invasive cancer and clinically negative axilla who underwent sentinel lymph node biopsy only (excluding patients who received primary systemic treatment), with a minimum standard of 90% and a target of 95% [14].

A database from EUSOMA started in 2006 showed that 61.5% of patients did not receive axillary clearance

(sentinel lymph node only), with an increase in the following years until reaching 96.7% in 2015 [28].

A study in different hospital settings in Portugal found that more than 90% of patients with early-stage breast cancer (stages I or II) and clinically negative axillary nodes underwent sentinel lymph node biopsy [12].

In Colombia, in stage I breast cancer, sentinel lymph node biopsy according to the developed model, is quite far from the minimum recommended standard (28.64% vs 90%) [14], and clearly, the percentage obtained with the model overestimates the real values because it includes some patients in stage II.

Clinical practice guidelines are widely used by medical teams, including physicians, nurses, and pharmacists, as a support tool for providing day-to-day evidence-based care [9]. The guideline of the Ministry of Health and Social Protection of Colombia described the evidence of sentinel node biopsy in breast cancer [21], and it is a recommended procedure in American guidelines [25].

There is consistency in the recommendation of clinical practice guidelines to perform sentinel lymph node biopsy in clinically node-negative early-stage breast cancer cases [16], although its validity should be periodically reviewed to evaluate modifications that arise from new evidence, such as the omission of sentinel lymph node biopsy in patients age ≥ 70 years with clinically node-negative (T1N0) early-stage invasive breast cancer, that is hormone receptor-positive and human epidermal growth factor receptor 2 (HER2)-negative [19]. In general, adherence to clinical practice guidelines has become a common tool to promote quality and equity of services and control costs [2]. When clinical practice guidelines are followed, clinical outcomes improve [11], which is why they are considered one of the few instruments to improve the quality of cancer care [15].

The low percentage of performance of sentinel lymph node biopsies in Colombia is expected to result in a higher rate of complications and higher costs for the health system. Greater efforts are required in the country to improve the care of patients with breast cancer.

There are several other ways to improve the quality of care. Access to rapid, high-quality diagnosis and multidisciplinary high-quality units is needed as well as advocacy, policy change, innovation, and strengthening of local research and training of specialists and subspecialists [30].

5. Conclusions

Sentinel node biopsy is currently the best approach for axillary staging in patients with clinically node-negative breast cancer. The performance of this procedure is considered to be an indicator of quality. The findings of this study suggest the need to increase the proportion of this surgery. To improve its performance, the management of breast cancer needs to be performed in comprehensive cancer centers in which care is provided by multidisciplinary teams. The government and the companies offering health services must do more to promote the quality of care for breast cancer.

Ethical considerations

This is considered risk-free research. This is a review whose evaluation base is statistical reporting; individuals are not evaluated.

Conflicts of interests

None.

Financial support statements

I did not receive any financial support for this research.

References

- [1] McDermott AM, Wall DM, Waters PS, Cheung S, Sibbering M, Horgan K et al., Surgeon and breast unit volume-outcome relationships in breast cancer surgery and treatment, *Ann Surg*, 258: 808–813, 2013. discussion 813–804. doi:10.1097/SLA.0b013e3182a66eb0.
- [2] Carlsen B, Glenton C, Pope C, Thou shalt versus thou shalt not: a meta-synthesis of GPs' attitudes to clinical practice guidelines, *Br J Gen Pract*, 57(545): 971–978, 2007. doi:10.3399/096016407782604820.
- [3] Desch CE, McNiff KK, Schneider EC, Schrag D, McClure J, Lepisto E et al., American Society of Clinical Oncology/National comprehensive cancer network quality measures, *J Clin Oncol*, 26: 3631–3637, 2008. doi:10.1200/JCO.2008.16.5068.
- [4] Colombian Fund for high-cost diseases, High-cost account. Cancer situation in the adult population served in the SGSSS of Colombia 2020. Bogotá DC, 2018–2021 (in Spanish).
- [5] Giammarile F, Vidal-Sicart S, Paez D, Pellet O, Enrique EL, Mikhail-Lette M et al., Sentinel lymph node methods in breast cancer, *Semin Nucl Med*, 52(5): 551–560, 2022. doi:10.1053/j.semnuclmed.2022.01.006.
- [6] Magnoni F, Galimberti V, Corso G, Intra M, Sacchini V, Veronesi P, Axillary surgery in breast cancer: an updated historical perspective, *Semin Oncol*, 47(6): 341–352, 2020. doi:10.1053/j.seminoncol.2020.09.001.
- [7] Iancu G, Mustata LM, Cigaran R, Gica N, Botezatu R, Median D et al., Sentinel lymph node biopsy in breast cancer. Principle, difficulties and pitfalls, *Chirurgia*, 116(5): 533–541, 2021. doi:10.21614/chirurgia.116.5.
- [8] Lyman GH, Giuliano AE, Sommerfield MR, Benson 3rd AB, Bodurka DC, Burstein HJ et al., American Society of Clinical Oncology guideline recommendations for sentinel lymph node biopsy in early-stage breast cancer, *J Clin Oncol*, 23(30): 7703–7720, 2005. doi:10.1200/JCO.2005.08.001.
- [9] Mukai H, Higashi T, Sasaki M, Sobue T, Time trends (2006e2015) of quality indicators in EUSOMA-certified breast centres, *IJQHC*, 28(1): 110–113, 2016. doi:10.1093/ijqhc/mzv109.
- [10] Verry H, Lord SJ, Martin A, Gill G, Lee CK, Howard K et al., Effectiveness and cost-effectiveness of sentinel lymph node biopsy compared with axillary node dissection in patients with early-stage breast cancer: a decision model analysis, *Br J Cancer*, 106(6): 1045–1052, 2012. doi:10.1038/bjc.2012.62.
- [11] Barth JH, Misra S, Aakre KM, Langlois MR, Watine J, Twomey PJ et al., Why are clinical practice guidelines not followed? *Clin Chem Lab Med*, 54(7): 1133–1139, 2016. doi:10.1515/cclm-2015-0871.
- [12] Rego IB, Coelho S, Semedo PM, Cavaco-Silva J, Teixeira L, Sousa S, 360 Health Analysis (H360)—A comparison of key performance indicators in breast cancer management across health institution settings in Portugal, *Curr Oncol*, 30(7): 6041–6065, 2023. doi:10.3390/curroncol30070451.
- [13] Biganzoli L, Cardoso F, Beishon M, Cameron D, Cataliotti L, Coles CE et al., The requirements of a specialist breast centre, *Breast*, 51: 65–84, 2020. doi:10.1016/j.breast.2020.02.003.
- [14] Biganzoli L, Marotti L, Hart CD, Cataliotti L, Cutuli B, Thorsten Kühn T et al., Quality indicators in breast cancer care: An update from the EUSOMA working group, *Eur J Cancer*, 86: 59–81, 2017. doi:10.1016/j.ejca.2017.08.017.
- [15] Levit L, Balogh E, Nass S, Ganz PA (eds), *Delivering High-Quality Cancer Care: Charting a New Course for a System in Crisis*, The National Academies Press (Washington, DC), 2013.
- [16] Vincent L, Margueritte F, Uzan J, Owen C, Seror J, Pouget N, Review of national and international guidelines for sentinel lymph node biopsy and complementary axillary dissection in breast cancer, *Bull Cancer*, 104(4): 356–362, 2017. doi:10.1016/j.bulcan.2017.01.001 (in French).
- [17] Amin MB, Edge SB, Greene FL, Byrd DR, Brookland RK, Washington MK et al. (eds), *The American College of Surgeons (ACS) (Chicago, Illinois). AJCC Cancer Staging Manual*, Springer, 2017.
- [18] Beek MA, Verheuveel NC, Luiten EJ, Klompenhouwer EG, Rutten HJT, Roumen RMH et al., Two decades of axillary management in breast cancer, *Br J Surg*, 102(13): 1658–1664, 2015. doi:10.1002/bjs.9955.
- [19] Brackstone M, Baldassarre FG, Perera FE, Cil T, Chavez M, Gregor M. et al., Management of the axilla in early-stage breast cancer: Ontario health (Cancer Care Ontario) and ASCO guideline, *J Clin Oncol*, 39: 3056–3082, 2021. doi:10.1200/JCO.21.00934.
- [20] Hewitt M, Simone JV (eds), *Ensuring Quality Cancer Care*. The National Academies Press (Washington, DC), 1999. <https://www.ncbi.nlm.nih.gov/books/NBK230933/>. Accessed July 3, 2023.
- [21] Ministry of Health and Social Protection - Administrative Department of Science, Technology and Innovation in Health

- (COLCIENCIAS). Clinical Practice Guideline (CPG) for the early detection, comprehensive treatment, follow-up, and rehabilitation of patients with breast cancer. Social Security System, Colombia, 2013. Guide No. 19. Colombia, 2013. ISBN: 978-958-57937-7-4. Bogotá, Colombia. Available at: <https://www.minsalud.gov.co/sites/rid/1/Gu%C3%ADa%20de%20Pr%C3%A1ctica%20Cl%C3%ADnica%20de%20Cancer%20de%20Mama%20versi%C3%B3n%20completa.pdf>. Accessed July 3, 2023 (in Spanish).
- [22] Bromham N, Schmidt-Hansen M, Astin M, Hasler E, Reed MW, Axillary treatment for operable primary breast cancer, *Cochrane Database Syst Rev*, 1(1): CD004561, 2017. doi:10.1002/14651858.CD004561.pub3.
- [23] Che Bakri NA, Kwasnicki RM, Khan N, Ghandour O, Lee A, Grant Y et al., Impact of axillary lymph node dissection and sentinel lymph node biopsy on upper limb morbidity in breast cancer patients, *Ann Surg*, 277: 572–580, 2023. doi:10.1097/SLA.0000000000005671.
- [24] National Cancer Institute from Colombia. Oncological services in Colombia. Bulletin 2. December 2017. Bogotá, Colombia. Available at: https://www.cancer.gov.co/recursos_user/files/libros/archivos/2017.Bolet%C3%ADn%20de%20servicios%20onc%C3%B3logicos#:~:text=En%20general%20la%20oferta%20de,atenci%C3%B3n%20de%20la%20enfermedad%20oncol%C3%B3gica. Accessed January 11, 2024 (in Spanish).
- [25] National Comprehensive Cancer Network. Guidelines. Available at: https://www.nccn.org/login?ReturnURL=https://www.nccn.org/professionals/physician_gls/pdf/breast.pdf. Accessed July 3, 2023.
- [26] Zork NM, Komenaka IK, Pennington Jr RE, Bowling MW, Norton LE, Clare SE et al., The effect of dedicated breast surgeons on the short-term outcomes in breast cancer, *Ann Surg*, 248: 280–285, 2008. doi:10.1097/SLA.0b013e3181784647.
- [27] Lovrics O, Tao B, Parvez E, Safety and accuracy of sentinel lymph node biopsy alone in clinically node-positive patients undergoing upfront surgery for invasive breast cancer: a systematic review, *Curr Oncol*, 30(3): 3102–3110, 2023. doi:10.3390/curroncol30030235.
- [28] van Dam PA, Tomatis M, Marotti L, Heil J, Mansel RE, Rosselli del Turco M et al., Time trends (2006–2015) of quality indicators in EUSOMA-certified breast centres, *Eur J Cancer*, 85: 15–22, 2017. doi:10.1016/j.ejca.2017.07.040.
- [29] Nsubuga P, White ME, Thacker SB, Anderson MA, Blount SB et al., Public Health Surveillance: A Tool for Targeting and Monitoring Interventions. Jamison DT, Breman JG, Measham AR et al. (eds), The International Bank for Reconstruction and Development/The World Bank (Washington (DC)), Oxford University Press (New York), 2006.
- [30] Nietz S, Ruff P, Carl Chen W, O’Neil DS, Norris SA, Quality indicators for the diagnosis and surgical management of breast cancer in South Africa, *Arch Gynecol Obstet*, 306(4): 1221–1234, 2022. doi:10.1007/s00404-022-06458-8.
- [31] Petousis S, Christidis P, Margioulas-Siarkou C, Liberis A, Vavoulidis E, Margioulas-Siarkou G et al., Axillary lymph node dissection vs. sentinel node biopsy for early-stage clinically node-negative breast cancer: a systematic review and meta-analysis, *Arch Gynecol Obstet*, 306: 1221–1234, 2022. doi:10.1007/s00404-022-06458-8.
- [32] Yen TWF, Laud PW, Pezzin LE, McGinley EL, Wozniak E, Sparapani R, Prevalence and consequences of axillary lymph node dissection in the era of sentinel lymph node biopsy for breast cancer, *Med Care*, 56(1): 78–84, 2018. doi:10.1097/MLR.0000000000000832.
- [33] TW Yen, PW Laud, Sparapani RA, Nattinger AB, Surgeon specialization and use of sentinel lymph node biopsy for breast cancer, *JAMA Surg*, 149: 185–192, 2014. doi:10.1001/jamasurg.2013.4350.