Original Article

# Regional anesthesia in breast surgery: An Italian expert consensus – Part 1: Methodology and Delphi strategy


## ABSTRACT

**Background:** Despite being considered routine, breast surgery is associated with a high incidence of acute and chronic postoperative pain, which can significantly impact recovery and quality of life. Regional anesthesia techniques have become increasingly relevant within multimodal analgesic strategies, yet clinical practice remains heterogeneous and lacks clear guidance. To address this, we aimed to develop a multidisciplinary, evidence-based consensus on the role of regional anesthesia in breast surgery.

**Methods:** An expert panel was appointed by the Italian Chapter of the European Society of Regional Anaesthesia, including anesthesiologists and breast surgeons (in partnership with the Italian National Association of Breast Surgeons). A four-round Delphi method was applied to refine an initial set of 24 PICO-formulated questions. Each question was evaluated for relevance and clarity using a 9-point Likert scale (1 = not relevant/clear, 9 = extremely relevant/clear). Finalized questions underwent systematic review or network meta-analysis depending on data availability.

**Results:** Eleven clinically relevant and clearly formulated PICO questions were identified after four Delphi rounds. These questions encompass acute and chronic pain control, block safety in anticoagulated patients, awake surgery, and the comparative efficacy of single-shot versus continuous blocks, among others. Each question will guide a systematic review and support the development of graded consensus statements.

**Conclusion:** This consensus project establishes a transparent, multidisciplinary framework for guiding the use of regional anesthesia in breast surgery. The ultimate objective is to formulate a set of consensus statements, graded according to evidence strength, which will serve as a foundation for future guidelines and standardized clinical decision-making.


**Key words:** Breast surgery, consensus, delphi consensus, regional anesthesia


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## Introduction

Breast surgery, whether conducted for cancer treatment or preventive measures, is one of the most commonly performed procedures among women worldwide.[1] Despite being considered routine, these surgeries carry a significant risk of both acute and chronic postoperative pain, which can greatly impact long-term quality of life.[2]

Chronic postsurgical pain (CPSP) can occur in up to 50% of patients, with moderate to severe pain persisting in 20–30% of cases 6 months after surgery.[3-5] This pain is often neuropathic and related to factors such as intercostobrachial nerve damage, axillary dissection, or inadequate early pain control.[6]

Acute postoperative pain is a recognized predictor of CPSP,[7] and an inadequate management of this pain can lead to a harmful cycle of escalating discomfort. Furthermore, psychological factors—such as preoperative anxiety, depression, and pain catastrophizing—can exacerbate the persistence of pain.[8] These factors contribute to delayed recovery, reduced physical function, and increased healthcare costs. Given the above picture, it is of paramount importance for a comprehensive, multidisciplinary perioperative approach that includes optimized pain management, psychological support, and collaborative decision-making. In recent years, regional anesthesia has emerged as a key component of multimodal analgesia in breast surgery and various regional techniques have been described to selectively anesthetize thoracic wall structures and for this reason could be applied for patients undergoing breast surgery, namely, thoracic paravertebral block, posterior chest wall blocks (erector spinae plane block, intertransverse process block, serratus posterior superior intercostal plane block), anterior chest wall blocks (interpectoral plane block, pectoserratus plane block, superficial/deep parasternal intercostal plane block, superficial/deep serratus anterior plane block), or a selective combination of these blocks. Each technique has its own anatomical targets, dermatomal coverage, clinical indications, and risk–benefit profile.[9-11]

Despite the increasing use of regional anesthesia techniques in breast surgery, current practices remain inconsistent.[12] Several factors influence the choice of anesthesia method, including institutional protocols, the expertise of the provider, patient comorbidities (such as anticoagulation), and the extent of the surgical procedure. Furthermore, advancements like continuous catheter techniques and the use of adjunctive medications (such as dexamethasone and dexmedetomidine) add more complexity to the standardization of these practices.[13]

Additionally, the application of regional anesthesia in awake breast surgery with sedation is receiving more attention as this approach may help decrease perioperative opioid use and improve recovery, especially in vulnerable patient populations.[14,15]

To address these uncertainties, a multidisciplinary consensus process is essential. This paper introduces the rationale and structure of a Delphi-based consensus initiative involving anesthesiologists, surgeons, and pain specialists. The goal is to identify evidence-based, safe, and practical recommendations for the use of regional anesthesia techniques in breast surgery, tailored to various clinical scenarios and patient profiles.

## Methods

The present project will follow the following steps to achieve its objectives, including: the composition of the expert panel, the selection and refinement of key questions (PICOs), a

systematic review of the literature to identify existing and recent evidence relevant to the defined PICOs, and the development of consensus statements.

a. Panel of experts

The expert panel will be established through a selection process coordinated by the Italian Chapter of the European Society of Regional Anesthesia (ESRA-IC). The society will identify leading Italian experts in regional anesthesia and collaborate with surgical societies to ensure a multidisciplinary perspective and enhance the validity of the final consensus statements. Selection criteria will include demonstrated scientific excellence, relevant peer-reviewed publications, and recognized expertise in the field. Once identified, experts will be formally invited via email. If there is no response within 1 week, a reminder will be sent, followed by a final reminder after another week. Lack of response to all email communications will be considered a formal decline of the invitation.

b. Questions selection (PICOS)

An iterative Delphi methodology[16] will be employed to develop and validate a set of relevant questions (PICOs) for the project. An initial steering committee, composed of ESRA-IC members (DPS, ADC, GM, FC, FP), will formulate a preliminary set of questions to be evaluated by an expert board.

Board members were asked to evaluate two aspects of each question: the relevance of content and the clarity of formulation. Evaluations were performed using a 9-point Likert scale (1 = not relevant/clear, 9 = extremely relevant/clear).

Additionally, respondents were provided with an open-ended comment section to elaborate on any lack of clarity or to justify low relevance scores.

Questions receiving a median score ≥7 in both relevance and clarity were considered appropriate and retained. Questions scoring below this threshold in either domain were returned to the Steering Committee for revision.

Revised items were resubmitted to the board in a subsequent round for re-evaluation using the same scoring procedure. This process was repeated iteratively until each question achieved a median score ≥7 in both criteria. Questions that scored below 7 in relevance for two consecutive rounds were considered nonessential and removed from the question pool.

c. Systematic review of the literature

A systematic review of the literature will be conducted to identify the most recent synthesized relevant scientific evidence related to the defined PICOs in the form of systematic review with or without meta-analysis. The queried database will be: PubMed, Embase, the Cochrane Library, and Scopus, while the searches will be formulated and developed in collaboration with an expert in systematic review and meta-analysis. Inclusion criteria will be predefined based on study design, population, intervention, and outcomes of interest, and the quality of the articles will be evaluated using the AMSTAR 2 tool.[17] Findings from all the retrieved reviews will be summarized and presented to the expert panel. In the event that no recent (18 months) meta-analysis will be found for some of the PICOs, a network meta-analysis (NMA) will be conducted to compare multiple interventions simultaneously and estimate their relative effectiveness. This approach allows for the integration of both direct and indirect comparisons across a network of studies, thereby enhancing the robustness and comprehensiveness of the evidence base.

c1) Network meta-analysis methods

A systematic search of the medical literature for the identification, screening, and inclusion of articles in the following database: PubMed, Embase, the Cochrane Library, and Scopus. For each database, a full search string will be provided to increase transparency and replicability.

No restrictions will be applied to the search; all databases will be queried from their inception to the date of the search, and studies in all languages will be considered. Only randomized controlled trials comparing any intervention with another intervention, placebo, sham block, or no intervention will be included in the quantitative analysis.

Two researchers independently will screen titles and abstracts of the identified papers in order to select relevant manuscripts. After identifying those studies meeting inclusion criteria, two authors will manually and independently review, assess, and extract the data from the included studies. For the outcomes regarding opioids, they will be converted into morphine equivalents (MME) using the GlobalRPh morphine equivalent calculator, considering 0% cross-tolerance modifier (http://www.globalrph.com/narcotic).

The quality of the included studies will be evaluated by two team members who independently evaluate the quality of included RCTs by using the Risk of Bias (RoB) 2 Tool.[18] Disagreements will be resolved by discussion; if agreement is not possible, a third researcher will be consulted.

Meta-analysis of data will be performed using R version 4.1 (R Foundation for Statistical Computing, Vienna, Austria) and the package 'netmeta'.

The treatment effect for continuous outcomes will be

expressed as mean difference (MD) or standardized mean difference (SMD) with 95% CI. The treatment effect for dichotomous outcomes will be expressed as risk ratio (RR) or odds ratio (OR) with 95% CI.

A ranking among methods will be performed based on the frequentist analog of the surface under the cumulative ranking curve.[19] Where necessary, we will convert reported median and interquartile range to estimated mean and standard deviation (SD) using Hozo's method.[20] We will not apply continuity correction to zero events.

The Chi-squared test and $I^2$-statistic will be used (considering $I^2$ values as follows: low: $<25\%$, moderate: 25% to 50%, or high: $>50\%$) to evaluate heterogeneity.[21] Within design heterogeneity and between design inconsistency will be evaluated using Cochrane Q. A random effect model was preferred regardless of both inconsistency and heterogeneity. Publication bias will be evaluated by a visual inspection of funnel plots.

d. Development of consensus statements

Following the systematic review and evaluation of the available evidence, the expert panel will develop consensus statements corresponding to each finalized PICO question. Draft statements will be formulated by the steering committee, integrating the findings from the literature and considering the quality and strength of the evidence. These preliminary statements will be circulated to the expert panel for structured evaluation using a Delphi approach. Each panel member will anonymously rate their level of agreement with each statement on a 9-point Likert scale (1 = strong disagreement, 9 = strong agreement). Consensus will be defined *a priori* as achieving a median score of $\geq 7$ with an interquartile range (IQR) $\leq 2$. Statements not reaching consensus will be revised based on qualitative feedback and re-evaluated in subsequent Delphi rounds. This iterative process will continue until consensus is achieved or the panel determines that agreement is unlikely. Final statements will be categorized according to the GRADE (Grading of Recommendations Assessment, Development and Evaluation) framework to reflect the strength and quality of the underlying evidence. The finalized consensus document will be peer-reviewed and submitted for publication in an indexed journal to ensure dissemination and transparency.

## Results

The Steering Committee was established on December 1, 2024 and was tasked with selecting the expert panel contributing to this consensus document. A total of 33 prospective board members were invited, all of whom accepted the invitation. Notably, the inclusion of the Surgical Society Italian National Association of Breast Surgeons (ANISC) was a strategic decision aimed at ensuring a multidisciplinary perspective, thereby broadening the scope and practical relevance of the project.

The Delphi process for PICOquestion selection underwent four iterative rounds: 24 questions in Round 1, 14 in Round 2, 11 in Round 3, and a final set of 11 revised questions in Round 4.

At each round, the Steering Committee independently scored each item for relevance and clarity using a 9-point Likert scale (1 = not relevant/clear, 9 = extremely relevant/clear).

Questions with a median clarity score $<7$ were retained but reformulated for the next round.

Questions with a median relevance score $<7$ were returned for revision; however, those that scored below this threshold in two consecutive rounds were considered nonessential and removed from the question pool.

As a result of this structured process, the following 11 PICO questions were finalized:

1. In patients undergoing simple mastectomy, or mastectomy with sentinel lymph node biopsy or axillary lymph node dissection, which of the following approaches—thoracic paravertebral block, anterior chest wall blocks, posterior chest wall blocks, or a selective combination of these blocks—is most effective in reducing intraoperative opioid consumption, postoperative pain, and the need for analgesics within the first 24 hours?
2. In patients undergoing simple upper/lower outer quadrantectomy or with sentinel lymph node biopsy or axillary lymph node dissection, which of the following approaches—thoracic paravertebral block, anterior chest wall blocks, posterior chest wall blocks, or a selective combination of these blocks—is most effective in reducing intraoperative opioid consumption, postoperative pain, and the need for analgesics within the first 24 hours?
3. In patients undergoing simple upper/lower inner quadrantectomy or with sentinel lymph node biopsy or axillary lymph node dissection, which of the following approaches – thoracic paravertebral block, anterior chest wall blocks, posterior chest wall blocks, or a selective combination of these blocks – is most effective in reducing intraoperative opioid consumption, postoperative pain, and the need for analgesics within the first 24 hours?
4. In patients undergoing major breast surgery, which

of the following approaches thoracic paravertebral block, anterior chest wall blocks, posterior chest wall blocks, or a selective combination of these blocks —most effectively reduces the incidence of chronic postoperative pain?

5. In patients undergoing minor breast surgery, which of the following approaches–thoracic paravertebral block, anterior chest wall blocks, posterior chest wall blocks, or a selective combination of these blocks —most effectively reduces the incidence of chronic postoperative pain?
6. In patients undergoing minor or major breast surgery, which of the following approaches—thoracic paravertebral block, anterior chest wall blocks, or posterior chest wall blocks—is associated with low incidence of complications rate?
7. In patients undergoing awake major breast surgery, which of the following approaches–thoracic paravertebral block, anterior chest wall blocks, posterior chest wall blocks, or a selective combination of these blocks—is most effective for performing the procedure under analgosedation with spontaneous breathing?
8. In patients undergoing awake minor breast surgery, which of the following approaches—thoracic paravertebral block, anterior chest wall blocks, posterior chest wall blocks, or a selective combination of these blocks—is most effective for performing the procedure under analgosedation with spontaneous breathing?
9. In patients undergoing major breast surgery, does continuous block provide better postoperative pain control within the first 24 hours compared to a single-shot technique?
10. In patients undergoing major and minor breast surgery, does intravenous dexamethasone or dexmedetomidine combined with local anesthetic prolong postoperative analgesia compared to local anesthetic block alone?
11. Which of the following approaches, thoracic paravertebral block, anterior chest wall blocks or posterior chest wall blocks, is safest in patients on anticoagulant or antiplatelet therapy?

## Discussion

Effective pain management in breast surgery remains a clinical priority, particularly given the high prevalence of both acute and chronic postoperative pain. The variability in regional anesthesia practices reflects ongoing uncertainty regarding the optimal technique for different surgical scenarios and patient populations. This consensus initiative, developed through a rigorous, multidisciplinary Delphi process, aims to address this variability by offering evidence-based, practical guidance for anesthesiologists and surgical teams.

The final PICO questions reflect the complexity of clinical decision-making in breast surgery, covering not only the effectiveness of various regional techniques for pain control but also their role in minimizing complications, enhancing recovery under analgosedation, and addressing high-risk populations, such as those on anticoagulants. By encompassing both major and minor surgical procedures, as well as continuous and single-shot approaches, the consensus statements are intended to support tailored, patient-centered analgesic strategies.

A critical strength of this project lies in its systematic methodology: the integration of high-quality evidence through systematic and network meta-analyses, the use of established frameworks such as PRISMA and GRADE, and the inclusion of diverse clinical perspectives from anesthesia, surgery, and perioperative care. The deliberate engagement of surgical societies further enhances the relevance and applicability of the recommendations in everyday practice.

While this initiative provides a structured foundation, it also highlights the need for ongoing research to validate and refine regional techniques in specific subgroups. Additionally, broader implementation may require institutional support, training, and resource allocation to standardize care across settings. Ultimately, this consensus represents a step forward in harmonizing perioperative pain management practices in breast surgery, with the potential to improve patient outcomes, reduce opioid reliance, and promote recovery in a vulnerable surgical population.

This multidisciplinary Delphi project distilled expert opinion and current evidence into a unified set of priorities for regionalanesthesia practice in breast surgery. By pairing a transparent consensus process with systematic and network meta-analyses, it creates a reliable platform on which future clinical guidelines and research can build. Adoption of the forthcoming recommendations should help standardize care, curb perioperative opioid use, and enhance both immediate recovery and longterm quality of life for women undergoing breast procedures.

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not involved in the consensus panel activities, their independent perspective was valuable in refining the final document.

### Author contributions

**Domenico P Santonastaso, Alessandro De Cassai, Eros Pilia, Francesco Coppolino, Gabriele Melegari, Federico Piccioni:**

Coordinated the expert panel organization, definition of PICO-based questions, management of the Delphi rounds, and validation of the final results.

**Paolo Scimia, Claude T Bagaphou, Antonio Coviello, Alessandra Morelli, Diego Marandola, Dario Pietrantozzi, Alessandra Gentili, Dario M Mattiacci, Giorgio Ranieri, Annabella de Chiara:**

Conducted or supervised the systematic review and/or meta-analyses used to inform the consensus process.

**Giuseppe Sepolvere, Federico Bizzarri, Fabio Costa, Mario Tedesco, Marco Rispoli, Cristiano D'Errico, Nicola Rocco, Moana R Nespoli:**

Actively participated in the Delphi rounds, providing item ratings, qualitative feedback, and contributing to the critical revision and discussion of the document.

**Pierfrancesco Fusco, Tommaso Tonetti, Secondo Folli, Annalisa Curcio, Andrea Tognù, Maria Caterina Pace, Fabrizio Fattorini, Giuseppe Lubrano, Vanni Agnoletti:**

Contributed to writing sections of the manuscript, ensured consistency of style and terminology, and participated in the final revision and approval of the document for publication.

**All listed authors have contributed substantially to the work, reviewed the manuscript, and approved its final version for submission and publication.**

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### Conflicts of interest

There are no conflicts of interest.

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