



# REVOLUTIONIZING WOMEN'S HEALTH CARE WITH A SUSTAINABLE CHANGE: BREAST GREEN SURGERY (BUGS) PROTOCOL

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**ABSTRACT – Objective:** Breast Cancer (BC) is the primary oncological diagnosis in women, with the annual incidence expected to exceed 3 million new cases by 2040 due to population growth and ageing. During the COVID-19 pandemic, novel methods were adopted to provide continuous care to patients, including the introduction of tele-health. This technique allows for improved access to care, reduced emissions with environmental impact, better resource utilization, and ultimately improved continuity of care. A current issue is the environmental impact of hospitals, particularly operating rooms, as it has been analyzed that 25-30% of hospital waste comes from these areas. In this regard, there has been a consideration to introduce the ERAS protocol, already active in colorectal surgery, into breast surgery, aiming to optimize resources, reduce hospital waste, and expedite waiting lists.

**Materials and Methods:** With the introduction of the Breast Green Surgery (BuGS) protocol, the focus is not only on creating a more environmentally sustainable operating room by reducing waste, but also on minimizing the anesthetic impact on the patient and the environment. It is known that volatile anesthetics significantly contribute to pollution.

**Results:** Our goal is to reduce their use by favoring awake surgery, using local anesthetics along with sedatives to maintain patient comfort during the procedure.

**Conclusions:** Therefore, our multidisciplinary BuGS protocol aims at evaluating for the synergistic effect of different procedures for the first time on Clinical Outcome, Patients' Reported Outcome Measure (PROM), and Environment Related Outcome Measure (EROM) in BC surgery.

**KEYWORDS:** Breast neoplasm, Breast surgery, COVID-19, Climate change, Green breast surgery, Green surgery, Quality of Life, Patient reported outcome measures.



## INTRODUCTION

Breast Cancer (BC) is the leading oncological diagnosis in women with an annual incidence of more than 2 million patients diagnosed<sup>1</sup>. Because of growing and ageing of population, by 2040 the BC burden is expected to spread over 3 million new cases and 1 million death every year<sup>2</sup>.

Previous studies have shown that utilizing a conservative approach in breast surgery, followed by radiotherapy, leads to higher overall survival compared to radical mastectomy<sup>3</sup>. In such research, survival with conservative surgery appears to be independent of prognostic factors, tumor characteristics, age, and type of therapy<sup>4</sup>. These findings have paved the way for improvements in patient anesthesiologic experience, transitioning from general anesthesia to awake surgery, aiming to reduce the impact of post-operative stress on patient recovery<sup>5</sup>.

Conservative surgery allows for a different anesthesiologic approach, shifting from general anesthesia to Monitored Anesthesia Care (MAC)<sup>6</sup>. This form of local anesthesia, accompanied by sedatives and analgesics dosed to allow spontaneous breathing and airway reflexes, promotes quicker post-operative recovery and less psychological impact on the patient compared to general anesthesia. A comparison between the two techniques was evaluated using the Quality of Recovery-15 (QoR-15) highlighted a higher score with the use of MAC<sup>6</sup>. Moreover, MAC reduces immunomodulation risk in the early post-operative setting, thus reducing potential long-term oncological outcomes on patients, and promoting a novel less immunosuppressive regimen in frail patients<sup>6-8</sup>. In fact, several studies in oncological patients demonstrated, in these subsets of patients, that the neoplasm may determine a subclinical impairment of immune response with abnormal response toward non-self or neoplastic cells<sup>9-11</sup>. In fact, in the era of precision oncology, synergistic effect between drugs, general health status (overweight patients) and BC are investigated to underline the beneficial role of general health measures in long term outcome<sup>12-15</sup>.

Additionally, the COVID-19 pandemic represented a practice-changing accelerator in many health care services. Many services tried to gather different procedures in a single hospital admission, in order to reduce the bed occupancy<sup>6</sup>. Among several innovation, a wider application of telehealth demonstrated that many consultations and healthcare services can be effectively delivered via digital platforms<sup>16,17</sup>. This approach has the potential not only to improve access to care but also to reduce the environmental impact associated with healthcare practices. As summarized in Table 1, telehealth in the context of BC not only offers advantages in terms of accessibility and continuity of care, but also promotes more sustainable healthcare practices, reducing the environmental impact of medical activities<sup>6,18,19</sup>.

**Table 1.** Beneficial effects of Telehealth on BC care.

Accessibility to care	Telehealth allows patients to access medical consultations and monitoring without the need to physically travel to healthcare facilities. This is particularly relevant for breast cancer patients as it reduces the need for travel during the course of treatment, while providing faster and more convenient access to healthcare resources.
Reduce GHG Emission	By eliminating or reducing patient and medical staff travel, telehealth helps decrease greenhouse gas emissions associated with transportation <sup>18</sup> . This aligns with efforts to make medical practices more sustainable, reducing the overall environmental impact of the healthcare sector.
Efficient resource utilization	Telehealth optimizes the use of hospital resources by reducing the need for physical space and specific equipment for on-site consultations <sup>19</sup> . This can contribute to more efficient management of healthcare resources, allowing for a greater focus on patient-directed care.
Continuity of care	In emergency situations such as the pandemic, telehealth has demonstrated the ability to ensure continuity of care, allowing patients to receive assistance without interruptions <sup>6</sup> . This is crucial, especially for oncology patients who require regular monitoring and consultations during their treatment journey.

Abbreviations – BC: Breast Cancer; GHG: Green House Gas.

Aside from mobility for hospital access, the healthcare industry and hospital facilities contribute to environmental pollution. It was estimated in 2013 that 12% of acid rain, 10% of greenhouse gases (GHG), 10% of smog, 1% of ozone gas depletion, and the production of atmospheric carcinogenic and non-carcinogenic toxins derive from healthcare activities within hospitals, with significant implications for public health<sup>20</sup>.

The increase in air pollution and consequently the risk of mortality has led to greater attention to new surgical protocols, which prioritize environmental needs in addition to patient clinical needs due to the resurgence of advanced-stage breast pathology, reduction of operating spaces, and dedicated hospitalization for individual patients. Hospitals and operating rooms represent the primary source of GHG emissions, with 25-30% of hospital waste being produced by operating rooms<sup>19,20</sup>.

Due to significant pollutant emissions, hospitals are a major source of environmental impact. In England, the National Health Service (NHS) alone is responsible for emitting 18 million tons of CO<sub>2</sub>, equivalent to 30% of GHG emissions from the entire public sector. Therefore, the NHS has initiated reflections and initiatives to make the healthcare sector carbon neutral. Four different intervention phases have been identified, highlighting that reducing CO<sub>2</sub> emissions in hospitals, especially in operating rooms, is not simple, mainly due to the current absence of specific guidelines aimed at gas reduction<sup>19</sup>. Evaluation parameters, feasibility, and safety have been introduced, expressing percentages at various points from a multicenter study that considers both physicians' and patients' opinions.

A large portion of hospital GHG emissions comes from the operating room, primarily due to the use of volatile anesthetics for general anesthesia. Among these, sevoflurane and desflurane are the main pollutants, from their production in the pharmaceutical sector to their impact on the atmospheric environment, where they persist for several years (1.4 and 21.4, respectively)<sup>21</sup>. These compounds act as GHG, contributing to global warming. Additionally, many volatile anesthetics contain nitrous oxide (N<sub>2</sub>O) as a carrier gas, which has a greater impact on global warming when mixed with ambient air<sup>22</sup>. This complex process, from pharmaceutical production to the atmosphere, represents a significant source of GHG originating from the hospital setting<sup>23</sup>.

It has been shown that reducing the use of anesthetics, especially the volatile ones, in surgery is possible, particularly highlighted by Wide-Awake Local Anesthesia No-Tourniquet (WALANT) surgery performed for small ambulatory hand operations. Patient satisfaction and better resource allocation are the most significant post-operative benefits of WALANT<sup>24</sup>. Studies have reported that 94% of patients would choose WALANT again in the future. Patients experience reduced post-operative pain compared to previous surgeries with tourniquet sedation. WALANT promotes better communication between the patient and the surgical team, enhancing understanding, compliance, and prevention of post-operative injuries. It reduces time spent in the post-operative phase, resulting in decreased costs for both the facility and the patient.

Reducing surgical impact has been a recent theme in general surgery. Since the 2000s, numerous authors have begun outlining the so-called Enhanced Recovery After Surgery (ERAS) protocols in general surgery, especially in colorectal surgery<sup>25,26</sup>. This multidisciplinary protocol aims to improve outcomes after surgery, articulating into four phases to ensure better control and greater adherence to the correct course: pre-hospitalization, pre-operative, intra-operative, and post-operative<sup>27</sup>. Regarding colorectal surgery, ERAS programs have shown improvements in post-operative hospitalization times, mortality, and consequently increased long-term survival. Specifically, in patients with ≥70% adherence to the ERAS protocol, the 5-year specific cancer death risk decreased by 42%.

From the results of studies conducted using ERAS and WALANT approaches, as well as telehealth assistance, it has emerged that their protocols can be effectively applied in breast surgery. In fact, in the recent years, awake surgery plus locoregional anesthetic regimen emerged as novel approach to accelerate postoperative recovery and minimize postoperative complication<sup>28,29</sup>. Consequently, our group is committed to implementing such studies and evaluating the results obtained.

The ERAS protocol can also be applied in the field of breast surgery, which, together with telehealth in the peri-operative and post-operative pathways, lays the groundwork for the Green Breast Surgery research project. This pathway is dedicated to patients undergoing conservative surgical treatment for breast pathology and is based on the analysis of clinical outcomes, quality of life, as well as social, environmental, and economic effects in the application of this telehealth protocol in clinical practice.

Limiting the resources applied in operating rooms allows for a greater number of patients to undergo surgical procedures, particularly in the field of senology. The reason why the Breast Unit is a good candidate for this type of protocol lies in the possibility of operating on the patient while awake, without the need for general anesthesia, due to the simplicity of the surgical procedure itself<sup>30</sup>.

A recent study has highlighted how climate change exacerbates health problems and creates new ones, particularly in low-income countries. Among the effects of climate change, increasing temperatures lead to a higher frequency of surgical site infections by up to 39%, while air pollution causes prolonged hospital stays and increased costs<sup>23</sup>. A table has been prepared with five different aspects of the surgical setting that can be improved, ranging from the use of non-volatile anesthetics to modifying some behaviors of operating room staff such as reducing the use of syringes, turning off lights when the operating room is not in use, and implementing telehealth instead of outpatient visits.

## MATERIALS AND METHODS

In the planning of a scientific study, it is necessary to establish inclusion criteria that determine who can be admitted to the research. These criteria are essential to ensure that the study population is homogeneous and that the results obtained are valid and generalizable. The inclusion and exclusion criteria are shown in Table 2.

**Table 2.** Inclusion and Exclusion criteria for the BuGS Study.

Inclusion Criteria	Exclusion Criteria
ASA1	Pregnant women
Female gender	Radical mastectomy procedure
Age between 18-95 years	Inadequate follow-up
Diagnosis of breast carcinoma	

The protocol is applied to all patients diagnosed with BC who meet the ASA1 inclusion criteria. Below are the recommendations of the ERAS protocol <sup>31</sup>.

### PRE-ADMISSION

- Conduct detailed counselling to adequately inform patients.
- Require a one-month smoking cessation period.
- Require a one-month alcohol cessation period.
- In cases of obesity, encourage weight loss until reaching a BMI below 30 to improve surgical outcomes and reduce surgical site complications.

### PRE-OPERATIVE

- Reduce the pre-operative fasting period by allowing clear fluids up to 2 hours before surgery.
- Administer maltodextrin (a soluble complex carbohydrate) 2 hours before surgery to improve insulin sensitivity, reduce thirst, and pre-operative anxiety.
- Prescribe antibiotic prophylaxis.
- Prescribe post-operative anti-nausea and anti-vomiting prophylaxis.

### POST-OPERATIVE

- Perform deep vein thrombosis (DVT) prophylaxis with heparin. Initially, categorize patients based on the risk of DVT, then administer prophylaxis for 7-10 days.
- Provide analgesic medications for pain control.
- Allow patients to consume food and water shortly after surgery.
- Promote patient mobilization a few hours after surgery.
- Use telehealth for follow-up visits.
- Evaluate quality of life using a specific score (PSQ-18<sup>32</sup>, SF-36<sup>33</sup>, Lancashire QoL score<sup>34</sup>, Breast-Q score<sup>35</sup>, TSQ-WT<sup>36</sup>).
- Monitor patient outcomes 30 days after surgery.

To ensure proper execution of the procedure, these checklists will help ensure that procedures in the green operating room and the conventional operating room are performed correctly and in accordance with their respective protocols.

Below, Table 3 summarized green breast protocol features in the Operating Room along with all its features, whereas in Table 4, Traditional Operating Room has been displayed.

**Table 3.** Green Breast Surgery Group protocol.**Checklist for GREEN OPERATING ROOM – 50 patients**

Welcome patients to the Breast Unit reception area on the morning of surgery
Optimize scheduled surgery lists
Operating room staff should not wear non-sterile gloves to move patients unless they come into contact with mucous membranes, biological fluids, or wounds
Awake surgery protocol for anesthesia
Divide instruments into two categories: those necessary for the procedure (scalpels, scissors, forceps, etc.) and optional but ready-to-use instruments
Implement waste separation (paper, plastic, glass, sharps, biological waste)
Monitor the number of staff in the room
Use a hand hygiene method without wipes
Use disposable chairs or chair covers in the recovery room
Reduce paper usage in packaging surgical gowns, trying to insert them into boxes with instruments
Reduce energy consumption, air conditioning, and lighting in unused rooms

**Table 4.** Traditional Operating Room protocol.**Checklist for TRADITIONAL OPERATING ROOM – 50 patients**

Welcome patients to the ward the day before surgery
Wear non-sterile gloves if you need to touch the patient
Use general anaesthesia
Prepare necessary and optional instruments for the procedure
Collect waste, separating contaminated from generic waste
Monitor the number of staff in the room
Follow the hand hygiene protocol
Use beds and supplies for patient recovery

**Statistical Analysis**

Data analysis will be conducted using Excel (Redmond, WA, USA) and SPSS software (Armonk, NY, USA). The data will be collected anonymously and will be crucial for evaluating various aspects:

- Clinical outcomes, such as the average reduction in postoperative hospital stay and the presence of surgical complications 48 hours after surgery.
- Patient quality of life outcomes, which will be assessed through validated scores in the population under study, such as the EORTC OUT-PATSAT 35 and the Telehealth Satisfaction Questionnaire (TSQ) scores, as well as the Breast-Q, SF-36, and QoL.
- Analysis of the environmental impact of the Green Breast Surgery protocol, which will include measuring kilometers travelled by private car and analyzing healthcare expenditure on consumables, both in general and specifically in plastics.

The study design will be a “Randomized Controlled Trial” (random clinical trial), which means that patients will be randomly assigned to one of the two treatment groups (Green Breast Surgery protocol vs. Traditional Operating Room protocol) to ensure the scientific validity of the results obtained. This type of study is essential for impartially evaluating the effectiveness and efficiency of the proposed protocol. Once obtained written informed consent all participants are randomly assigned to one of the groups (Green Breast Surgery protocol vs. Traditional Operating Room protocol).

## Study Objective

The objective of the study is focused on analyzing the potential environmental, clinical, and organizational effects of implementing the Breast Green Surgery protocol (BuGS protocol) in daily clinical practice. This study aims to develop a new surgical protocol directed at improving the aspects mentioned earlier.

The BuGS protocol will be extended to all patients undergoing conservative breast surgery in a benign context. This decision was made considering the impact that breast pathology has on women mental health and overall well-being. Therefore, we deemed it appropriate to implement a study project aimed at reducing hospitalization, which will involve patients without known oncological pathology.

In the context of this study, all patients will undergo so-called “awake” surgery protocols as described earlier, allowing for rapid discharge within 3 hours of the end of the surgical procedure. Access to the operating room will be directly from the reception area of the Breast Unit at Policlinico Tor Vergata (Rome, Italy).

After the conclusion of the procedure, all patients will undergo careful clinical observation and continuous monitoring of vital signs for a period of approximately 3 hours. At the end of this observation phase, patients will be instructed on the use of any drains and wound care to be applied at home. Subsequently, they will be discharged with all necessary instructions to participate in a surgical telehealth follow-up appointment, to be conducted one week after the procedure, as well as a physical medical visit scheduled two weeks after the procedure.

The first visit, conducted via a dedicated software (Microsoft Teams, Redmond, WA, USA) provided by Policlinico Tor Vergata (Rome, Italy), will allow patients to access post-operative follow-up, while simultaneously reducing the environmental impact resulting from patient travel and hospital overcrowding.

## CONCLUSIONS

The objective of this research is to implement strategies aimed at rationalizing resources in the medical field of breast surgery to ensure a reduction in economic and environmental impact, thereby improving sustainability in the surgical field. It is crucial to also consider the surgical outcome in terms of post-operative pain at 48 hours, 7 days, and 30 days<sup>37</sup>.

The primary objective of implementing the awake surgery protocol is to control post-operative pain at 48 hours, 7 days, and 30 days measured using the VAS scale. Additionally, the study endpoint aims to promote faster patient discharges, thus significantly reducing costs associated with hospital management, including plastics, disposable materials, and linens, which represent a significant component of healthcare expenses. Furthermore, this strategy aims to reduce environmental impact by decreasing waste generated by such disposable materials, thereby contributing to environmental sustainability.

Another crucial objective is to reduce hospital visits, which should lead to a decrease in transportation costs and, particularly, provide a valuable solution in logistical deficient areas lacking adequate public transportation systems such as metro, train, and bus. By reducing the number of patients needing to travel to the hospital for post-operative check-ups and visits, it will both improve patient quality of life and reduce the environmental impact associated with travel, promoting greater sustainability in such areas.

### AUTHOR CONTRIBUTIONS:

Conceptualization: Gianluca Vanni, Oreste Claudio Buonomo, Marco Materazzo; Methodology: Marco Pellicciaro, Sabrina Chemello, Giorgio Lisi, Sebastiano Angelo Bastone; Writing – Original Draft: Sabrina Chemello, Denisa Eskiu, Giorgio Pistilli; Writing - Review & Editing: Marco Materazzo, Gianluca Vanni, Valentina Marsella, Fabrizia Calenda, Benedetto Longo; Supervision: Oreste Claudio Buonomo, Nicola Di Lorenzo, Valerio Cervelli.

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Not Applicable.

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The authors declare there is no conflict of interest.

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