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Insights on DRGs, guideline compliance and economic sustainability. The case of mastectomy with immediate breast reconstruction

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Abstract

Background. *Immediate breast reconstruction is recommended for eligible patients undergoing mastectomy, raising the issue of economic sustainability of both mastectomy and breast reconstruction performed within the same hospitalization, as opposed to two surgical procedures in two different hospitalizations.*
Study design. *A retrospective analysis was conducted to compare economic sustainability of mastectomies with or without immediate breast reconstruction.*
Methods. *Economic data on hospitalizations for mastectomy in a Teaching Hospital between 1 January 2019 and 31 March 2021 were analyzed to assess their sustainability.*
Results. *338 admissions were selected (63.9% with immediate breast reconstruction (CI 99%: 57.2% to 70.6%). Compared to mastectomy alone, mastectomy with immediate breast reconstruction had higher cost of € 2,245 ($p < 0.001$), with operating rooms and devices as main cost drivers. Current reimbursements rates (which are the same for mastectomy alone and for mastectomy with immediate breast reconstruction) led to an average loss of € 1,719 for each mastectomy with immediate breast reconstruction.*
Conclusion. *Current DRGs reimbursement rates for hospital admissions for breast cancer surgery do not guarantee immediate breast reconstruction's economic sustainability. DRGs system should be revised, or other solutions as bundled payment should be implemented in the light of the costs of innovation in*

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healthcare, considering mastectomy and breast reconstruction steps in a path of linked actions aimed at improving patients' health.

Introduction

Breast cancer is the most frequent in Italy: in 2019, there were more than 53,000 new cases (1) and more than 62,000 hospitalizations for malignant breast cancer surgery (2).

According to the 2020 Brest Cancer Guidelines of the Italian Association of Medical Oncology (AIOM), immediate breast reconstruction (IBR), i.e. reconstructive surgery in the same operating session of mastectomy, is desirable for every patient undergoing mastectomy, as it improves women's quality of life (3) and several studies and reviews have highlighted its benefits, primarily with respect to the psychological impact (4, 5). IBR, on the other hand, does not increase the risk of recurrence or delay in recurrence diagnosis (4, 6) and it is generally considered a safe procedure with an acceptable complication rate (7, 8).

Affordable economic coverage of breast reconstruction is generally decisive for the accessibility of this procedure (9). Several studies have been carried out on the influence that payers and fees have on gaining access to breast reconstructions, especially in countries with a private insurance health system (10-13). In countries with a National Health Insurance Service (NHIS), such as Korea, IBR's proportion increased after the inclusion of its NHIS coverage (14).

In a universalistic health system, mastectomy with IBR, as opposed to mastectomy alone and reconstructive surgery alone, raises the issue of addressing costs arising from both demolition and reconstructive surgery carried out within a single hospitalization with a single refund, instead of costs of the two separate procedures carried out in two different hospitalizations with two different reimbursements. This is an issue of best practice sustainability in healthcare, concerning hospital refund rates. In fact, since mastectomy and reconstructive surgery have different costs, hospitalizations for mastectomy with reconstructive surgery are more expensive than those for mastectomy alone or reconstructive surgery alone. Therefore it would be appropriate to distinguish reimbursements rates for demolition with IBR from those for demolition or reconstruction only. This is to avoid healthcare professionals choosing the most economically advantageous but least appropriate option that is to perform the two procedures separately in two different hospitalizations, in order to get two reimbursements for the Hospital instead of just one.

Since January 1st 1995, Italy has adopted the DRGs (Diagnosis Related Groups) system to classify and reimburse acute hospital admissions. The current national refund rates have been enacted in 2012 (15). DRGs need regular updates as disease classification, clinical practice, health technologies and related costs evolve (16). From a legislative point of view, DRGs should be updated every two years, but although a project to their update is underway at national level (It.DRG Project (17)), this need is substantially still unfulfilled (18).

The two national DRGs 258 and 257 classify and reimburse hospital admissions for total mastectomy without and with complications respectively (15).

The Lazio Region DRG rates have been updated in 2013, by implementing the 2012 national measure, and the DRGs 258 and 257 amount, respectively, to € 3,341 and € 3,948 for hospitalizations longer than one day and within the length of stay threshold limit (19).

In other Italian Regions, the DRG rates have been updated with respect to those issued at national level in 2012, based on costs currently incurred by hospitals. For example, in the Veneto Region DRGs 258 and 257 amount respectively to € 4,168 and € 5,540 (20).

Payment systems have long been recognized as tools for clinical governance in general, and differences between regional and national fee schedules have already been studied for their potential to discourage opportunistic behaviors and promote virtuous ones (21).

Concerning breast cancer, guidelines (3) recommend IBR after mastectomy when appropriate and Italian institutional bodies have included this recommendation into the national system of healthcare quality indicators. In particular, the proportion of IBR performed in the same session as the demolition surgery for malignant breast cancer is monitored, with a minimum standard set at 40%. A high proportion of women undergoing mastectomy with IBR identifies quality in healthcare for breast cancer (22).

But have hospital reimbursement rates also been consequently updated by National and Regional Health Service to make this model of care sustainable?

The aim of this study is to analyze economic data (essentially costs and revenues) of hospitalizations for total mastectomy in a Teaching Hospital in Rome (Lazio Region) in order to assess the IBR sustainability, as well as to simulate a scenario based on the application to the Lazio Region of the most up-to-date refund rates in force in another Italian Region.

Material and methods

This study is compliant with the Local Ethical Committee Standards of the Fondazione Policlinico Universitario Agostino Gemelli (FPG) Scientific Research and Care Institute (IRCCS). It was carried out in accordance with the Helsinki Declaration and EU Regulation 2016/679 (GDPR).

A search has been conducted by accessing the FPG repository for aggregated and anonymized data on hospital admissions between 1 January 2019 and 31 March 2021, according to the following criteria:

- elective admissions resulting in DRG 258-257;
- paid for by the Regional Health Service;
- with a hospital stay within the threshold and longer than one day;
- with only one surgical session during hospitalization;
- with at least one of the following surgical procedures reported in the hospital discharge form (Scheda di Dimissione Ospedaliera, SDO): bilateral radical mastectomy; unilateral radical mastectomy; unilateral enlarged radical mastectomy; bilateral enlarged simple mastectomy; unilateral simple enlarged mastectomy; bilateral simple mastectomy; unilateral simple mastectomy; unilateral subcutaneous mammectomy.

Hospitalizations and surgeries thus selected have been successively stratified according to the presence or absence, in the SDO, of breast reconstruction procedures: uni/bilateral implantation of prosthesis; total breast reconstruction; breast tissue expander insertion.

It has been decided not to consider sentinel lymph node biopsy or axillary lymphadenectomy but just classify the interventions in *mastectomy alone* or *mastectomy and IBR*.

Hospitalizations' average revenues, costs and margins (i.e. the difference between revenues and costs incurred by the Hospital) with a 99% confidence interval (CI) have been analyzed. Costs have been stratified as follows: average length of stay cost; average length of stay in intensive care unit (ICU) cost; average cost of operating rooms (ORs); average cost of devices; average cost

of other healthcare services provided during hospitalization.

Differences in average revenues and costs have been tested through T-Test, setting the significance level to $p < 0.01$.

Finally, a scenario has been simulated in which the real revenues based on the Lazio Region DRG refund rates have been replaced by the revenues that would have been get if the same hospitalizations had been valued based on the up-to-date reimbursement rates of the Veneto Region.

Results

Three hundred thirty eight admissions met the inclusion criteria (corresponding to 338 different patients and 338 accesses to the operating room, one per admission). Among the 338 patients, 216 underwent both mastectomy and IBR, the remaining 122 underwent mastectomy alone. Hospitalizations and surgeries with both mastectomy and IBR accounted for 63.9% of the total sample (CI 99: 57.2% to 70.6%).

Average costs and revenues (99%CI) are reported in Table 1.

Average revenues for mastectomy (€ 3,569 to € 3,711) and mastectomy with IBR € 3,517 to € 3,621) are comparable (as expected, since they result in the same DRGs, 258 and 257, and therefore in similar refund rates). On the other hand, margins are significantly different. In fact, mastectomy shows a positive margin (thus helping to offset overhead and indirect costs incurred by Hospital to ensure healthcare), but mastectomy with IBR (the majority of surgical procedures analyzed) shows a largely negative margin, generating an average economic loss (Table 1).

As expected, costs difference between hospitalization for mastectomy alone and hospitalization for mastectomy and IBR is attributable to operating rooms (ORs) and devices costs. In fact, an operating session in which IBR is added to mastectomy is more expensive (€ 3,819 to € 4,225) than the one for mastectomy only (€ 1,579 to € 2,151) (Table 1).

Even costs of hospital stay are significantly different between the two types of hospitalization (€ 914 to € 1,058 of hospitalizations for mastectomy vs € 1,093 to € 1,192 of the ones for both mastectomy and reconstructive surgery), due to a difference, upstream, in the average length of stay (3.08 days; CI 99%: 2.86-3.31 vs 3.57; CI 99%: 3.41-3.72 respectively).

ICU cost, having a negative CI lower limit (Table 1), is to be considered statistically irrelevant in generating costs for these patients, whether they receive mastectomy alone or both mastectomy and IBR. In fact, only 5 out 338 patients went to ICU, for a total number of 7 days of hospitalization in this setting, vs 1,147 days of hospitalization in the ordinary inpatient setting.

Table 1 - Average costs and revenues of the selected admissions

Average cost and revenue items	Mastectomy alone	Mastectomy and IBR
Real DRG	€ 3,569 to € 3,711	€ 3,517 to € 3,621
Hospital Stay	€ 914 to € 1,058	€ 1,093 to € 1,192
ICU	€ -34 to € 133	€ -9 to € 31
Operating Rooms	€ 1,384 to € 1,707	€ 2,768 to € 2,993
Devices	€ 164 to € 475	€ 1,006 to € 1,277
Other healthcare services	€ 108 to € 176	€ 98 to € 128
Margin	€ 251 to € 944	€ -1,951 to € -1,487
N	122	216

Table 2 - Mastectomy and IBR vs mastectomy only: difference of hospitalizations' average costs and revenues

Average cost and revenue items	Difference 99% CI	p-value
Real DRG*	€ - 125 to € 49	0.039
Hospital Stay	€ 70 to € 242	< 0.001
ICU	€ -125 to € 49	0.256
Operating Rooms	€ 1,141 to € 1,529	< 0.001
Devices	€ 614 to € 1,030	< 0.001
Other healthcare services	€ -67 to € 8	0.044
Margin	€ -2,722 to € -1,911	< 0.001

*Lazio Region's DRG rates

Table 3 - Comparison of economic margins resulting from the Lazio and Veneto Regions' DRG rates implementation

CI 99%	Real scenario (Lazio Region's DRG rates)	Simulated scenario (Veneto Region's DRG rates)	T-test p-value
DRG	€ 3,553 to € 3,637	€ 4,645 to € 4,835	< 0.001
Total Costs	€ 4,234 to € 4,721	€ 4,234 to € 4,721	NA
Margin	€ -1,131 to € -634	€ -2 to € 528	< 0.001

The T-test confirms a statistically significant difference for average costs of ORs, devices, and Hospital stay, as well for average margins (Table 2).

Simulating a scenario in which, with steady Hospital costs, the Veneto Region's DRG rates are applied to the analyzed 338 selected hospitalizations, the average margin shows a significant increase ($p < 0.001$) (Table 3).

Discussion and conclusion

This study assessed the IBR's economic sustainability starting from the analysis of FPG's hospitalizations for mastectomy and highlighting the need to revise and update the DRG system's reimbursement rates.

FPG is one of the most important breast center in Italy (2) and is ranked by both National and Regional Outcomes Programs among the best hospitals for surgical care quality of breast cancer patients in Italy and Lazio Region (23-25). The results of our study about the IBR proportion are consistent with the results published by the regional and national agencies. From our data, FPG's IBR proportion is 63.9% (CI 99%: 57.2% to 70.6%) compared to official data, which report, for 2019, a FPG's IBR proportion of 65.3% (versus a national average of 51.7%) (22).

FPG implements the most up-to-date evidence and guidelines on breast reconstruction in the clinical management of breast cancer patients, despite the current national and regional DRG reimbursement system clearly penalizes adherence to best practice. In fact, according to our analysis results, unlike other health systems and contexts (13, 14), IBR is provided by FPG to patients despite the consequent economic loss to the Hospital due to an outdated DRG system. The clinical management of patients who cannot benefit IBR and receive only mastectomy is sustainable for the Hospital, with current reimbursement rates. Vice versa, management of patients who, in compliance

with guidelines and quality indicators, can access both mastectomy and IBR in the same operating session, leads to an economic loss for the Hospital, which, nevertheless, continues to provide its patients a high standard of care quality.

These findings clearly show that mastectomy with IBR is significantly more expensive, particularly due to costs of ORs and devices, than mastectomy only. This data should induce payer to reconsider and revise both the classification of hospital admissions for breast cancer surgery and the related reimbursement rates. In fact, considering that DRGs were introduced to classify and pay for hospital services (26), in order to make their best use as a governance tool, the continuous updating of the DRG classification, besides performance quality control systems, is essential (27).

This study also shows a difference in the length of stay (and consequently costs) of mastectomy only vs mastectomy with IBR. Patients who undergo mastectomy with IBR have, on average, a length of stay only half a day longer than patients undergoing mastectomy only, with an average higher cost of only € 156 (to make a comparison, the average difference in costs of ORs and devices for the two types of hospitalization amounts to € 2,157). An increased hospital stay, however, could be justified not only by the higher complexity of the intervention with both surgical procedures, but also by the double risk, as reported by some authors, of surgical site infection after mastectomy with IBR vs only mastectomy (28). Anyway, the average hospital stay of the selected admissions was 3.41 days, lower than the national average of 3.77 days (29), confirming the FPG's considerable breast surgery performance.

Based on these considerations, it is more than evident that to make IBR economically sustainable, which is a standard recommended by guidelines and good practices, an update of its reimbursement rates is needed. To this purpose, the most intuitive strategy consists in revising the DRG system, which can be done in two ways: a) introducing, beside those already existing, new DRGs for mastectomy with reconstruction covering the average costs resulting from the two surgical procedures performed within the same hospitalization; b) updating the existing DRGs by increasing the amount of their reimbursement rates, so as to ensure a balance between costs and revenues, which is the case of the Veneto Region (30). The simulation carried out in this study shows that applying the Veneto Region's DRG rates - instead of the Lazio Region's ones - to the same hospitalizations, better economic results would have been achieved, allowing to make mastectomy with IBR more sustainable.

Further solutions to the sustainability issues, beside reviewing and updating DRGs, can be identified in other forms of payment for hospitals, e.g. payment per function (31) and bundled payment or episode-based payment (32, 33).

Payment per function consists of assigning a function budget to the reference centers identified by the Health Authority among healthcare providers according to specific quality criteria, as is the case of breast centers identified by the Region within its cancer network (34). This form of payment has the aim of ensuring both healthcare quality and economic sustainability of the most important providers in the care pathways, which have to face costs resulting from high quality care for a complex casuistry, especially when DRG rates are not profitable enough to cover the costs incurred by Hospitals.

The bundled payment, also known as episode-based payment, is defined as a kind of providers' refunding, aimed to cover the costs of the whole care process. It has already been studied for breast reconstructions. In fact, the complexity of the care processes of patients with breast cancer is leading to identify new payment systems that take into

account the whole process of care/packages of related activities (bundling). This new thinking does not consider mastectomy a separate clinical activity from the others, and therefore to be reimbursed to hospitals separately from other treatments, but a step in a path of linked actions aimed at improving patients' health, to be reimbursed as a services' package. This may also significantly impact on the IBR accessibility (32).

To our knowledge, none of these solutions have been effectively implemented to date, neither at national level nor in the Lazio Region, although policymakers are aware of the issue and agree on the need to identify solutions. A regional Lazio law, dating back to February 27, 2020, explicitly states that IBR is promoted by the Lazio Region, which will carry out all measures aimed to ensure its concrete implementation" (35). The COVID-19 pandemic has plausibly further slowed down an already delayed process, especially considering the strong impact of the epidemic on hospital care in the Lazio Region (36) which made it necessary to update the COVID-19 patients classification (37) and the related hospital reimbursement rates (38).

The impact of the DRG-based payment system on innovation in healthcare in the Italian context has been already assessed by several studies. It is widely recognized that delays in updating hospital admissions' classifications (and therefore reimbursement rates) are a brake on innovation in healthcare (39). Indeed, the last significantly impacts on costs of clinical management, due to expensive new hospital health technologies (40) or changing clinical practice (41). Understanding the drivers of cost growth is essential for pursuing clinical governance (40), and using DRGs as a governance tool requires continuous updating of hospital admissions' classifications and their reimbursement rates (16, 27).

The present study, carried out in a Teaching Hospital, analyzed costs and revenues of admissions for a specific health condition and the impact that sustainability issues related to the guidelines compliance of its clinical management could have on clinical and organizational appropriateness.

The findings of the study, focused on breast cancer surgery, could inspire further investigations to confirm the need, even in other clinical settings, for reviewing and updating DRGs, in the light of the costs of innovation in healthcare techniques and health technologies, to guarantee economic sustainability. Moreover, the study results could be the subject of discussion, at national and regional level, between providers and institutional health bodies to inform and support the health policy and decision making.

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Riassunto

Analisi di DRG, aderenza alle linee guida e sostenibilità economica: il caso delle mastectomie con ricostruzione immediata

Premessa. La ricostruzione mammaria immediata è raccomandata per tutte le pazienti eleggibili sottoposte a mastectomia, ponendo la necessità di approfondire la sostenibilità economica dell'offrire alla pazienti sia la demolizione che la ricostruzione mammaria nella stessa ospedalizzazione, piuttosto che due distinte procedure in due distinte ospedalizzazioni.

Disegno dello studio. È stata condotta un'analisi retrospettiva per confrontare la sostenibilità economica delle mastectomie con o senza ricostruzione mammaria immediata.

Metodi. Sono stati analizzati i dati economici relativi alle ospedalizzazioni per mastectomia tra il 1° gennaio 2019 ed il 31 marzo 2021 in un policlinico universitario.

Risultati. Sono stati incluse 338 ospedalizzazioni (63.9% delle quali con ricostruzione mammaria immediata (IC 99%: da 57.2% a 70.6%). Rispetto alla sola mastectomia, la mastectomia con ricostruzione mammaria immediata ha generato costi maggiori di circa 2,245 euro ($p < 0.001$), principalimente attribuibili ai costi delle

sale operatorie e dei medical device. Le attuali tariffe di rimborso (le stesse sia per la sola mastectomia che per la mastectomia con ricostruzione mammaria immediata) hanno portato ad una perdita economica media di 1,719 euro per ogni mastectomia con ricostruzione mammaria immediata.

Conclusioni. Le attuali tariffe associate ai DRG per la remunerazione dell'assistenza ospedaliera non tutelano la sostenibilità economica delle mastectomie con ricostruzione mammaria immediata. Il sistema di pagamento a DRG dovrebbe essere rivisto, o altre soluzioni come i rimborsi per processo dovrebbero essere implementate alle luce dei costi dell'innovazione in sanità, considerando la demolizione e la ricostruzione del seno due tappe di un unico percorso volto a tutelare la salute delle pazienti.

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