Relationship Between Price and Diagnosis-Related Group Tariff for Medical Devices Assessed by a Regional Health Technology Assessment Committee

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Abstract
Introduction
Medical devices (MDs) make up an important share of total in-hospital expenditure. At the level of individual patients, this share is represented by the ratio of the cost of MD incurred by the patient vs. the total cost of in-hospital care for the same patient. If tariffs rather than costs are considered, the denominator of this ratio is given by the diagnosis-related group (DRG) and the ratio is the cost of MD over DRG tariff. The objective of this paper is to present a retrospective analysis comparing the ratio of price vs. DRG tariff for a group of devices belonging to risk class III or active implantable. These devices are those assessed in the years 2020 and 2021 by two committees of the Tuscany region in Italy.

Materials and methods
The information on price and DRG was taken from the health technology assessment (HTA) reports concerning MDs evaluated by the two above-mentioned regional committees in the years 2020 and 2021. In these reports, the information on the cost-effectiveness ratio was reported for a subset of MDs. In all cases, a preliminary qualitative assessment was carried out to determine the presence or absence of a healthcare impact in the post-discharge phase. In these preliminary analyses, the perspective of NHS was adopted.

Results
Our analysis was focused on 24 devices of either class III or active implantable. According to our results, a wide variability was found in the ratios between device price and DRG associated with its use. This ratio ranged from a minimum of about 3% in the case of the Hyalobarrier gel (Nordic Pharma GmbH, Zürich, Switzerland) for post-surgical adhesion to a maximum of 132% in the case of the Neovasc Reducer (EPS Vascular AB, Viken, Sweden), a device indicated in the narrowed coronary sinus. Three devices, i.e., PuraStat (3-D Matrix, Ltd., Tokyo, Japan), Atesy Medical Dissection Stent (AMDS, CryoLife, Inc., Kennesaw, GA), and Tendyne (Abbott Cardiovascular, Plymouth, MN), were found to be priced more than the reimbursement tariff (i.e., ratio > 100%). Ratios between 50% and 100% were found in about half of the devices. From our preliminary assessment on the presence of a post-discharge impact, 15 devices out of 24 (62%) were found to determine a substantial impact, while the remaining nine (38%) did not. In general, when costs and benefits of a device do not extend beyond the patients’ discharge, the presence of a ratio > 100% reliably suggests the conclusion that the device price needs to be reduced and/or the tariff needs to be increased. On the other hand, in cases where the device extends its impact beyond the patient’s hospital stay, the decision of reducing price or increasing tariff becomes more complex, and so these adjustments cannot be determined unless more information on some critical aspects is made available.

Conclusions
Until the above-mentioned improvements do not take place, rational interventions on DRG are virtually unfeasible owing to this lack of critical information. On the other hand, it is also difficult to intervene on device prices, again owing to the lack of critical information.

Categories: Healthcare Technology, Health Policy
Keywords: hta, value-based purchasing, drg-s, cost-effectiveness analysis, high-cost medical devices

Introduction
Some classes of medical devices (MDs) make up an important share of total in-hospital expenditure
information needed for our analysis. Figure by GRDM and CHTA. The six devices left out from the present report were excluded owing to the lack of basic

The analysis included 24 (80%) of the 30 devices of class III or active implantable evaluated in 2020 and 2021

Results

Economic analysis is complex because the NHS perspective must be applied so that determinants of cost and
effectiveness result from patient’s hospital stay. On the other hand, the more complex situations are those
where this post-discharge impact occurs and is relevant in clinical and economic terms. In these cases, the
effectiveness of these devices. Finally, a qualitative assessment is reported for each device about

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The information on price, DRG, and any further parameter concerning cost-effectiveness was taken from the
HTA reports of MDs evaluated by the two above-mentioned regional committees in the years 2020 and 2021.
These reports are published in the specific section of the website of the Tuscany region [3]. In these reports,
the information on cost-effectiveness, when available, is of fundamental importance because it allows
comparing the clinical benefit with the cost of the MD concerned and, in general, to compare the cost-
effectiveness profiles across devices belonging to the same therapeutic class. In cases where a formal study
on the cost-effectiveness ratio was not available for the MD concerned, a preliminary qualitative assessment
was carried out to determine the presence or absence of a healthcare impact (clinical and/or economic) in a
post-discharge time horizon. In these preliminary analyses, this impact was assessed according to the NHS
perspective, which includes both the hospitalization period and the post-discharge period. The societal
perspective was not adopted because this would have required the evaluation of indirect costs as well. In the
first place, these analyses allowed to identify the situations where this post-discharge impact does not occur;
in such cases, a very simple analysis appears to be acceptable in which the analytical perspective is restricted
to the hospital (without extending to the community) and in which factors determining cost and
effectiveness result from patient’s hospital stay. On the other hand, the more complex situations are those
where this post-discharge impact occurs and is relevant in clinical and economic terms. In these cases, the
economic analysis is complex because the NHS perspective must be applied so that determinants of cost and
effectiveness can be thoroughly assessed after the patient’s discharge.

Results

The analysis included 24 (80%) of the 30 devices of class III or active implantable evaluated in 2020 and 2021
by GRDM and CHTA. The six devices left out from the present report were excluded owing to the lack of basic
information needed for our analysis. Figure 1 shows the flow diagram of our analysis.
FIGURE 1: Flow diagram describing our research.
HTA, health technology assessment; DRG, diagnosis-related group.

In our results (Table 1), a wide variability was found in the ratio between device price and DRG associated with its use. This ratio ranged from a minimum of about 3% in the case of the Hyalobarrier gel (Nordic Pharma GmbH, Zürich, Switzerland) for post-surgical adhesion to a maximum of 132% in the case of the Neovasc Reducer (EPS Vascular AB, Viken, Sweden), a device indicated in the narrowed coronary sinus.

| Name of the device                                      | Unit price (euro) | DRG code* (description) | DRG tariff\(|\) (euro) | Ratio of MD price versus DRG tariff (%) | Post-discharge impact determined by the MD** (Y/N) | Cost-effectiveness analysis of MD |
|--------------------------------------------------------|-------------------|--------------------------|-------------------------|----------------------------------------|--------------------------------------------------|-------------------------------|
| 1. Neovasc Reducer (EPS Vascular AB, Viken, Sweden): coronary sinus reducer stent | 6,500             | 556 (Percutaneous interventions on the cardiovascular system without major cardiovascular diagnosis with bare-metal stents) | 4,889                   | 132.0                                  | Yes                                              | The cost-effectiveness ratio is favorable considering a Neovasc Reducer price of 7,000 euros [4] |
| 2. PuraStat (3-D Matrix, Ltd., Tokyo, Japan): hemostatic hydrogel | 300               | 412 (Anamnesis of malignant neoplasm with endoscopy) | 230                     | 130.4                                  | No                                               | Not available                  |
| 3. Ascyrus Medical Dissection Stent, AMDS (CryoLife, Inc., Kennesaw, GA): hybrid aortic system for dissections | 13,000            | 105 (Heart valve surgery without cardiac catheterization) | 25,000                  | 52.0                                   | Yes                                              | Not available                  |
|                                                        |                   | 110 (Major interventions on the cardiovascular system with complications) | 14,200                  | 91.5                                   | Yes                                              | Not available                  |
| 4. | Tendyne (Abbott Cardiovascular, Plymouth, MN): transcatheter mitral valve replacement | 28,000 | 111 (Major interventions on the cardiovascular system without complications) | 10,500 | 123.1 | 24,115 | 116.1 | Yes | Not available |
| 5. | Cardioband (Edwards Lifesciences, Irvine, CA): tricuspid valve reconstruction system | 22,000 | 104 (Heart valve interventions and other major cardiothoracic interventions with cardiac catheterism) | 22,115 | 99.5 | Yes | Not available |
| 6. | Pascal Mitrale Ace (Edwards Lifesciences, Irvine, CA): mitral valve transcatheter repair system | 22,000 | 104 (Heart valve interventions and other major cardiothoracic interventions with cardiac catheterism) | 24,115 | 91.2 | Yes | The cost-effectiveness ratio is favorable considering a Pascal price of 20,000 euros [5] |
| 7. | Pascal Tricuspid Ace (Edwards Lifesciences, Irvine, CA): tricuspid valve transcatheter repair system | 22,000 | 104 (Heart valve interventions and other major cardiothoracic interventions with cardiac catheterism) | 24,115 | 91.2 | Yes | The cost-effectiveness ratio is favorable considering a Pascal price of 20,000 euros [5] |
| 8. | Pascal (Edwards Lifesciences, Irvine, CA): mitral valve transcatheter repair system | 20,000 | 104 (Heart valve interventions and other major cardiothoracic interventions with cardiac catheterism) | 22,115 | 90.4% | Yes | The cost-effectiveness ratio is favorable considering a Pascal price of 20,000 euros [5] |
| 9. | Braxon (DECOmed, Marcon, Italy): acellular dermal matrix breast reconstruction | 2,939 | 258 (Total mastectomy for malignant neoplasms without complications) | 3,341 | 88.0 | No | Not available |
| 10. | Megasystem (Waldemar Link GmbH, Hamburg, Germany): modular shoulder prosthesis | 7,000 | 491 (Interventions on major joints and upper limb reimplant) | 8,822 | 79.3 | No | Not available |
| 11. | QuiremScout (Quirem Medical B.V., Deventer, The Netherlands): bead diagnostic device | 3,000 | 203 (Malignant neoplasms of the hepatobiliary system or pancreas) | 4,208 | 71.3 | No | Not available |
| 12. | Micra AV Model MC1AVR1 (Medtronic Europe, Tolochenaz, Switzerland): leadless ventricular pacemaker | 8,500 | 110 (Major interventions on the cardiovascular system with complications) | 14,208 | 59.8 | Yes | Not available |
| 13. | Cardia Ultrasound Aria (Cardia Inc., Eagan, MN): atrial septal defect closure device | 3,750 | 518 (Percutaneous interventions on the cardiovascular system without stent insertion into the coronary artery without myocardial infarction) | 9,881 | 38.1 | Yes | Not available |
| 14. | EkoSonic (EKOS Corporation, Bothell, WA): catheter-directed thrombolysis | 3,000 | 075 (Major interventions on the chest) | 8,737 | 34.3 | Yes | Not available |
| 15. | Impella RP (Abiomed, Danvers, MA): percutaneous ventricular assist device | 18,000 | 525 (Implantation of other cardiac assistance systems) | 53,272 | 33.8 | Yes | Not available |
| 16. | IntellaNav StablePoint (Boston Scientific, Marlborough, MA): ablation catheter incorporating local impedance data | 2,200 to 2,600 | 555 (Percutaneous interventions on the cardiovascular system with major cardiovascular diagnosis) | 9,283 | From 23.7 to 28.0 | No | Not available |
| 17. | Konar VSD Occluder (LifeTech, 2022 Trippoli et al. Cureus 14(3): e23092. DOI 10.7759/cureus.23092 | 33x802 to 74x811 | 4.10.7759/cureus.23092 | 4 of 9 |
### TABLE 1: Ratio of MD price versus DRG tariff, post-discharge impact, and cost-effectiveness ratio of MD.

| Device Description                                                                 | Price  | DRG Code | Ratio | Impact | Cost-Effectiveness | Notes |
|------------------------------------------------------------------------------------|--------|----------|-------|--------|--------------------|-------|
| Petaling Jaya, Malaysia): transcatheter closure of ventricular septal defect       | 4,000  |          |       |        |                    |       |
| 18. Protek Duo (LivaNova, London, UK): right ventricular assist device              | 5,350  |          |       |        |                    |       |
| 19. His Bundle Kit 3D (BIOTRONIK, Berlin, Germany): introduction system for implantation of leads in sites specifications and lead | 500    |          |       |        |                    |       |
| 20. Avalus (Medtronic Europe, Tolochenaz, Switzerland): stented bovine pericardial aortic bioprosthesis | 2,200  |          |       |        |                    |       |
| 21. BioFreedom (Biosensors International Ltd, Singapore): polymer-free drug-coated stents | 515    |          |       |        |                    |       |
| 22. TriGUARD 3 (Keystone Heart, Ltd., Tampa, FL): cerebral protection device        | 1,950  |          |       |        |                    |       |
| 23. Destino Twist (OSCOR Inc., Palm Harbor, FL): steerable sheath                  | 800    |          |       |        |                    |       |
| 24. Hyalobarrier gel (Nordic Pharma GmbH, Zürich, Switzerland): auto-crosslinked hyaluronan gel for adhesion prevention in laparoscopy and hysteroscopy | 145    |          |       |        |                    |       |

* Diagnosis-related group; § regional tariff, see [2]; ** clinical and/or economic impact. MD, medical device; DRG, diagnosis-related group.

Besides Neovasc Reducer, three other devices, i.e., PuraStat (3-D Matrix, Ltd., Tokyo, Japan), Ascyrus Medical Dissection Stent (AMDS, CryoLife, Inc., Kennesaw, GA) when used according to DRG 111, and Tendyne (Abbott Cardiovascular, Plymouth, MN), were found to be priced more than the reimbursement tariff (i.e., ratio > 100%). Ratios between 50% and 100% were found in about half of the devices. Information on cost-effectiveness was not available for most devices. This was mainly due to the insufficient clinical evidence available, which is typical of devices, particularly those in the first phases of marketing. Unfortunately, this lack of information on cost-effectiveness did not allow us to carry out a pharmacoeconomic comparison of most new devices with those already available in our hospitals. This unavailability of information equally affected both the clinical side and the economic one. Finally, from our preliminary assessment on the presence of a post-discharge impact, 15 devices out of 24 (62%) were found to determine a substantial impact after discharge, while the remaining nine (38%) did not.
Discussion

In the first place, evaluating the post-discharge impact of the 24 devices included in Table 1 was an original finding of our study because, as confirmed in the Appendix, this point has not been addressed in the literature previously. As regards the subgroup of nine devices with no impact after discharge, their clinical-economic impact was restricted to the patient’s in-hospital stay and therefore implied no particular complexity; in fact, when the costs and benefits of a device do not extend beyond the patient’s discharge, the presence of a ratio > 100% reliably suggests that either the device price needs to be reduced or the tariff needs to be increased; the analysis in these cases is straightforward irrespective of which decision is needed.

On the other hand, in cases where the device extends its impact beyond the patient’s hospital stay, the decision of either reducing the price or increasing the tariff becomes complex. This is because a large number of factors are involved in both the hospital stay and the post-discharge phase. Among these factors, the clinical benefits achieved by the patient after discharge and the long-term savings resulting from the consequent reduction in healthcare costs are particularly difficult to be assessed. Hence, a full clinical-economic assessment would be needed in these cases, but the analysis is always complex. For example, this scenario applies to Neovasc Reducer, AMDS, and Tendyne, whose ratios between price and tariff are higher than 100%. To a lesser extent, this also applies to Cardioband, Pascal Mitraille Ace, Pascal Tricuspid Ace, Pascal, and Micra, whose price-to-tariff ratio is between 50% and 100%.

In summary, adequate governance of MDs can be achieved when an insufficient DRG is combined with the absence of a post-discharge clinical-economic impact. On the other hand, the analysis is complex when an insufficient DRG is combined with the presence of a post-discharge clinical-economic impact.

When the price/DRG ratio is high and a full economic analysis is unavailable, selecting the most appropriate corrective interventions is difficult; in particular, it is difficult to estimate which monetary increase would be needed in the DRG or which reduction in the device price. This suggests that a sound governance of costs and benefits in the field of high-technology devices is not presently achievable unless the two following points are substantially improved: (1) the quality of patient-related information both in hospital stay and in the post-discharge phase; and (2) the human resources allocated to HTA at public institutions with the purpose of managing and interpreting information on costs and benefits.

Our literature search also identified the previously mentioned paper [1] published by our group in 2020. In comparing the present analysis with that published in 2020, one substantial difference emerges because the ratio price/DRG was calculated for a small number of individual devices in the present analysis whereas, in our previous analysis, this calculation was applied to an entire hospital or an entire region. The implications raised by these two types of analysis are different, but both estimates of this ratio can be useful because, in this way, the same issue is examined from two different perspectives: the one focused on a single treatment or procedure (according to which decisions can be made on device procurement) and the one focused on the hospital or region (according to which decisions can be made about the governance of the healthcare system).

In the light of our findings, an adequate quantification of the main clinical and economic parameters related to the in-hospital use of MDs seems to be unlikely within the present organization of hospitals and the current level of patient traceability. In particular, an improvement is needed in the collection of patients’ in-hospital information as well as in the out-of-hospital monitoring of patient-related events. Until these improvements do not take place, it is difficult to intervene on DRGs owing to this lack of critical information. Well-known delays in the update process of Italian DRGs have also contributed to this negative scenario.

On the other hand, it is also difficult to intervene on device prices, again owing to the lack of critical information. In theory, the price should be proportionate to the extent of clinical benefit, but since the data on the efficacy and safety of MDs are limited, in most cases, one cannot establish which prices are cost-effective and which are not.

Our work has documented a small part of this overall problem since our analysis examined only a small number of devices (i.e., class III and active implantable devices) proposed for inclusion as new products in the regional formulary. To assess the real economic impact of MDs in our NHS and highlight the potential discrepancies between price versus reimbursement tariffs, analyses like ours should hopefully be extended to include the large number of high-cost devices regularly purchased through regional tenders. Potential candidates for these further analyses include implantable defibrillators for which the relationship between price and reimbursement is between 42% and 90%. Likewise, percutaneous aortic valves are another critical device class whose price represents approximately 85% of the DRG.

As regards the limitations of the present work, while conducting our analysis was straightforward owing to its descriptive nature, its main weakness depends on the lack of some essential information that would be required to carry out a cost-effectiveness assessment. The main problem in the Italian national health system (and in the Tuscany region as well) consists in the poor quality of computerized medical records,
especially within hospitals. In particular, no efficient systems are available that allow for an exchange of patients’ medical records across different hospitals. Instead, the availability of a detailed patient’s history is a key factor to adequately assess costs and benefits, especially in chronic diseases that require a long-term follow-up.

In this overall context, the French experience of MD governance, developed over the past few years, is particularly interesting [6]. In France, institutions that manage devices for in-hospital use have in fact undertaken some original pathways of governance. One of these is based on a regularly updated list of MDs, especially the most expensive and innovative ones, that are funded separately from DRG tariffs. In more detail, while most MDs are managed in France according to the "traditional" reimbursement rule based on DRG ("intra-DRG list"), a number of devices are managed separately from DRGs and, in more detail, are included in the so-called "additional list." These devices are in fact reimbursed outside the DRG based on a separate funding pathway [6].

Finally, it should be kept in mind that while the combination of an insufficient DRG with the presence of a post-discharge clinical-economic impact is an important negative factor in terms of governance, other factors are involved too. Among these, one seems to be particularly important: the combination of an insufficient DRG with the presence of post-discharge clinical benefits encourages, albeit unintentionally, the inter-regional mobility from less developed regions toward more developed regions (where the degree of development is intended in terms of quality of hospital health care). In fact, the technologically "backward" regions, which have not equipped themselves to promptly implement innovations at their own facilities, are inappropriately rewarded if they promote regional mobility of specific patients so that they reimburse - at low DRG tariffs - patients treated with innovative services that other more advanced regions have implemented and can provide to these patients. At the same time, these less advanced regions can derive an undeserved economic advantage from the reduction in healthcare costs incurred by patients in their region of residence, thanks to the successful treatment received in another region [7].

A final point deserves to be mentioned. In the Tuscany region, the yearly expenditure for MDs is, more or less, similar to that of pharmaceutical products. The expenditure for MDs is mainly restricted to hospitals in a context where the upwards trend in this expenditure is growing rapidly. In contrast, a large part of the expenditures for pharmaceuticals takes place in the community where the economic trend is stable. This trend observed in the Tuscany region for both devices and pharmaceuticals is essentially the same as in the other Italian regions.

Conclusions

In the field of MDs, the current scenario in terms of governance is likely to improve over the next years. Some Italian regions such as Tuscany have implemented new HTA activities specifically focused on MDs. One such example is represented by the analysis presented herein. Although the scientific literature about MDs remains scarce in Italy, the presence of these new activities will hopefully yield positive effects on the regional governance of these products and, consequently, also in terms of scientific impact.

Appendices

This appendix presents a PubMed search of articles focused on the relationship between device price and DRG tariff. Figure 2 shows the PRISMA (Preferred Reporting Items for Systematic Reviews and Meta-Analyses) flow chart of this search (and related keywords). A total of 710 citations were selected at first extraction; then, a subset of "pertinent" articles (n = 195) was identified by checking abstracts individually and selecting articles that dealt with one or more devices as well as their DRG tariffs. Investigators who authored these articles were in a large proportion clinicians who worked in a hospital setting (n = 190; 97%). A small number of these articles (n = 2; 1.5%) were authored by the institution responsible for the payment of the procedure. Only two studies (1%) were authored by the manufacturer of the device. The overall picture that emerges from this PubMed search is characterized by an overall small number of studies on these topics, given that the entire world literature was examined. On the other hand, the group of 195 "pertinent" articles showed a clear fragmentation of results because their focus was generally limited to a single device or procedure, and no systematic review was found that evaluated different devices or procedures in terms of price and tariffs. Further details on the 710 articles included in this analysis are available as a preprint in reference [8].
Additional Information

Disclosures

Human subjects: All authors have confirmed that this study did not involve human participants or tissue.

Animal subjects: All authors have confirmed that this study did not involve animal subjects or tissue.

Conflicts of interest: In compliance with the ICMJE uniform disclosure form, all authors declare the following: Payment/services info: All authors have declared that no financial support was received from any organization for the submitted work.

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