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ORIGINAL PAPER

How much for the fusion biopsy. Cost analysis of the prostate ultrasound guided biopsy in the era of multiparametric MRI, preliminary results

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SUMMARY

Introduction. *Prostate cancer has an important incidence and mortality yet the best diagnostic procedure is to be defined. The latest scientific works aim at the use for diagnostic purposes of multiparametric magnetic resonance (mpMRI) according to the Pirads 2 criteria.*
The aim of the work is to quantify the overall cost of the diagnosis obtained with the use of mpMRI before the transrectal eco-guided prostate biopsy and to evaluate the economic impact of some current-use prostate biopsy strategies such as cognitive fusion biopsy, software fusion and with the Target or Target strategy with a systemic scheme.
Material and methods. *The total cost of mpMRI-guided transrectal biopsy was determined by referring to the experience of 289 procedures performed in 2017. The following cost factors were assessed: personnel, materials, maintenance - equipment depreciation, energy consumption and common costs of structure. A review of the literature was also performed to verify the correspondence of the costs that we extrapolated with those of other international operating entities and to consider the "cost of the mpMRI-guided transrectal agobiopsy" in the context of the broader debate on the effectiveness of the strategies for the early diagnosis of prostate cancer.*
Results. *The overall cost of the transrectal mpMRI guided biopsy was 531,00 if performed with cognitive fusion; data obtained by adding together the costs of: personnel (E. 243,00); materials (E. 178,00); maintenance - depreciation of equipment (E. 72.30); energy consumption (E. 0.20); general costs of hospital care (E. 37.500), to be added the cost of amortization of hardware and software for computer-assisted fusion, this depends on the initial purchase cost and the number of annual biopsy procedures, if the ultrasound is not dedicated only to biopsies but is also used for other procedures the costs are spread over a greater number of procedures and so they go down. It can be assumed that for 300 procedures a year the impact of a fusion machine can add from 40 to 120 E to each procedure according to the initial cost of the machine, maintenance, any dedicated consumables, and operator time.*

KEY WORDS: *Prostate cancer, fusion biopsy, ultrasound, mpMRI.*

No conflict of interest declared.

INTRODUCTION

The literature review points out transrectal ultrasound guided biopsy (TRUSB) as an invasive tool for diagnosing prostatic carcinoma clinically and economically controversial. Post mortems report the presence of cancer cells in the prostate of 50% of 70-year-old men, while extrapolations calculate a morbidity from prostatic carcinoma in 9.5% of 50-year-old men (1, 2). It is therefore obvious that randomised prostatic biopsies, methods apart, have a good probability of being positive (1, 2). This probability varies with the patient\quote and age, the level of prostate specific antigen (PSA), the density of PSA/cm3 of prostate volume (PSAD), detection by digital exploration and/or positive transrectal ultrasound (2).
Despite severe application of all these criteria and critical assessment of the patient\quotes general conditions, TRUSB was indicated for 16% of the male population over 50 years old, with obvious economic consequences (1, 2).
The introduction of multiparametric Magnetic Resonance Imaging of the prostate (mpMRI) is deeply changing the diagnostic path for prostate cancer (3-9).
A biopsy is the only way for a definitive diagnosis of prostate cancer (1). In Italy the cost of transrectal prostate biopsy was calculated in 1998 and based on the sextant scheme in use in those years and the "Lire" the old Italian currency (10).
Then It was calculated the costs in Euro in 2011 (11)
The purpose of this study was to assess how the introduction mpMRI, and the platform for fusion biopsy have affected the costs of the procedure.
The procedure need a mpMRI analized by an expert Radiologist, the biopsy device, with or without a fusion device a transrectal ultrasound probe, the needle and some disposable items (glove, plastic sheet, needle guidance, gel).
The full cost to perform the biopsy is the sum of the costs of all resources involved in performing this biopsy method. The cost of mpMRI is the real cost of the execution of the

procedure, the costs of personnel and the amortization of the hardware used for other procedures (12, 13).
Were analyzed and reported costs of each element that is involved in fusion prostatic biopsy separately.

Methods

The total cost of mpMRI -guided biopsy was determined referring to the experience on 289 procedures run in 2017; with standard 12 samples plus 2-4 target biopsy, we calculated the cost of target only biopsy too, there were evaluated the following cost factors: personnel, materials (principals,drugs and films), maintenance and depreciation of equipment, energy consumption and cost of the property (imputed rent of the premises and participation in the overall costs of the hospital).
All resource costs involved in the process were calculated on a purchasing power of the EURO 2017.
Indirect costs such as lost work time from the patient, the cost related to the loss of free time, the cost of transporting the patient, the time to reach the hospital and the costs related to complications were not calculated. This kind of costs are theoretical and go further the purpose of this analysis and dealing with uncertainty are very difficult to estract. So only direct costs are examined (12, 13).
As for the cost of personnel, are involved in the procedure as more professionals, it's down in the detail of the implementing rules by identifying, for each individual operator, 3 phases of activity:
1) a preliminary examination, such as the acceptance (phase A);
2) real execution (phase B);
3) after execution, such as reporting (phase C).

For each of these phases and for each professional has been computed the execution time, its cost and the cost arising from the sum of all these phases and operators: cost of direct labor (13).
The execution time of mpMRI ultrasound-guided biopsy was set at optimal operating conditions: cooperative patient, experienced operator, logistics and environmental well suited.
In addition to the cost of work done for the direct execution of the procedure (direct labor costs) were also counted any additions or corrections due to operational difficulties for patients poorly collaborating to unpredictable environmental disruptions, weariness of the professionals operating (cost of average time burden).
Finally it was also considered the cost of time to activities not directly related to the execution of the procedure, but indispensable to the life and service management: inventory management, archive, scientific activities, updating, management (labor costs indirect) (12, 13).
It 'was also carried out a review of the literature in order to verify the correspondence of our data compared with those of other international and operational realities that figure "cost fusion biopsy ultrasound-guided" in the context of the broader debate about the' cost-effectiveness of strategies for early detection of prostate cancer (14-20).

Results

The overall cost of TRUS-guided prostate biopsy (12 sample) without mpMRI and fusion devices, was still around € 250 euro as in 2011 (11) (**Table 1**). In detail, personnel costs are € 98.40 for the results of direct business, which must be added € 34.80 for corrective (average cost of a burden) and more € 26.80 for the indirect business.
These data were obtained by adding up the costs of:
a) personnel (doctor sampler, pathologist, pathology technician,nurse and secretary) of E. 160,000;
b) materials (cutting needle, syringe, gloves, prepared slides; and 8 tablets of cotrimoxazole) equal to E. 59,000 (addi-

Table 1. Overall costs of systematic and targeted prostate biopsy (cognitive vs mpMRI/TRUS fusion procedure).

Procedure costs EURO (€)	Systematic prostate biopsy (12 cores) €	Targeted "cognitive" fusion biopsy €	mpMRI/TRUS fusion biopsy €
Personell*	160.00	243.00	243.00
Materials**	78.00	178.00	178.00
maintenance and depreciation of equipment	12.30	72.30	72.30
energy consumption°	0.20	0.20	0.20
overhead costs of the hospital°°	17.50	27.5	27.5
energy consumption	0.20	0.20	0.20
Ultrasound fusion device/platform	-	-	49/120.00
Overall cost €	250.50	531.00	571/651.00

*doctor sampler, pathologist, pathology technician, nurse and secretary;
** cutting needle, ultrasound, optical microscope, computer, printer, furnishing of the premises, syringe, gloves, prepared slides and antibiotic;
°ultrasound, optical microscope, computer, printer, furnishing of the premises;
°°proportion of use of the ambulance service, anesthesia and resuscitation service, salaries of health care and administrative leadership

tional 19,000 are added to E if the appeals echogenic needle Chiba;
c) maintenance and depreciation of equipment (ultrasound, optical microscope, computer, printer, furnishing of the premises, etc.) equal to E.12,300;
d) energy consumption at a flat rate of E. 0,20;
e) overhead costs of the hospital (proportion of use of the ambulance service, anesthesia and resuscitation service, salaries of health care and administrative leadership, etc.) equal to E. 17,500.

In detail, personnel costs are 98,400 euros for the results of direct business, which must be added E. 34,800 for corrective (average cost of a burden) and more E. 26,800 for the indirect business.
In the case of supplementary biopsies, exceeding the maximum of 12 standardized methodology "to the sextant," there was a relative increase in costs due to increased unloading time and reading time. In fact, this possibility of little impact on the average total duration of the sampling procedures and preparation of samples will be prepared if you sent in the box associated with the transport (up to 3 carrots for "cage", so do not affect the average total consumption of materials and of medical devices, its cost has been calculated under "corrective" to direct work. It would be calculated in about E 20,00 more expense, bringing the total sum at E. 270,00 for the procedure.
The average cost for mpMRI was 281 E (staff cost Radiologist and radiologic technician 163,00 E, equipment cost (119,00 E).
Results. The overall cost of the transrectal mpMRI guided biopsy was 531,000 if performed with cognitive fusion; data obtained by adding together the costs of: personnel (E. 243,000); materials (E. 178,000); maintenance - depreciation of equipment (E. 72.300); energy consumption (E. 0,20); general costs of hospital care (E. 37.500), to be added the cost of amortization of hardware and software for computer-assisted fusion, this depends on the initial purchase cost and the number of annual biopsy procedures, if the ultrasound is not dedicated only to biopsies but is also used for other procedures the costs are spread over a greater number of procedures and so they go down. It can be assumed that for 300 procedures a year the impact of a fusion platform can add from 40,00 to 120,0 E to each procedure according to the initial cost of the machine, maintenance, any dedicated consumables, and operator time that it is usually tripled in the fusion method (loading of the mpMRI exam, extrapolation of the images, choice of target, synchronization of the mpMRI and ultrasound images).

Discussion

The total cost of mpMRI cognitive fusion biopsy (21, 23) is in our esperienze E. 531 E, substantially corresponding to data reported in the literature (24).
For diagnostic tests and staging methods, the variations in the resource costs between the United States and other countries were mixed. The pooled baseline resource costs were 2.3 times higher in the United States than in other countries (24).
The item that affects more (64%) between the cost factors is related to personnel; on this item will therefore focus attention on identifying and streamlining procedures to reduce spending, especially with regard to the corrective work is directed (14% of total) and indirect (10%).
Another possible area of spending restraint, certainly more effective, is the rational use for mpMRI: in this sense moves the search for guidelines in the diagnosis of prostate cancer (1).
The inclusion of fusion biopsy mpMRI-guided as a step in a protocol of early diagnosis of prostate cancer is controversial from economic points of view (5-7), because reported resource costs for performing biopsy and clinical staging represented combined resource costs from several procedures, they should be interpreted with caution. Furthermore, reported resource costs for performing mpMRI and/or biopsy did not include the cost of complications resulting from these procedures. It has been reported that complication costs are directly correlated to the biopsy rate. Resource costs associated with complications arising from biopsy should be reported separately from those for diagnostic procedures because the cost of complications depends on the number of infections, which ranges from 5% to 6%, and their severity (25, 26).
The only way to reduce costs is reducing the number of negative (useless biopsy), in this way mpMRI could give some help (8, 9).
The actual costs for the average patient seeking a first-line biopsy would actually include:
- The costs for the initial MRI;
- The costs for the evaluation of the results of that MRI (as evaluated by an experienced and skilled uroradiologist);
- The costs for the systematic, 12-core, TRUS-guided biopsy, and;
- The costs for the MRI/TRUS fusion-guided biopsy.

Despite the rigorous application of all these criteria and the critical evaluation of the general state of the patient, as many as 16% of the male population over 50 years old only with PSA and the rectal findings maintain the indication to the eco-guided transrectal agobiopsy prostate, which has a reasonable economic weight. Recently, the use of mpMRI as a strategy to reduce the use of biopsy and increase its diagnostic efficacy would appear to be of clinical utility. We have calculated the costs of this approach. It is more difficult to calculate the effects of this approach at a distance, to check whether reducing the number of samples obtained reduces complications. If you decide not to biopsy negative mpMRI patients (21% or more of the population examined) the savings would be 250 E per patient (calculated on all patients who would have been biopsy candidates). Reducing the number of samples obtained at each biopsy would halve the costs of pathological anatomy.
These phases are evaluated and an aggregate risk for a particular lesion being cancerous is given by the radiologist, commonly as a PI-RADs score (6). Using this score, MRI provides an accurate diagnostic tool in prostate cancer with high specificity for high grade disease (6). The negative predictive value of MRI also provides an opportunity to

delay or avoid a biopsy in cases where no lesion is detected (8, 9). This could reduce both the cost of the biopsy and the potential risk of serious complications, such as sepsis, whose incidence is rising due to increasing rates of quinolone resistance (25, 26). Post-biopsy sepsis, while rare, is serious for those patients affected and costly to the healthcare system (27). Many cost studies assume that MRI negative patients would not undergo biopsy, however omission of systematic ultrasound guided biopsies may miss relevant cancers and may not reflect real-world practice (15).

An earlier Dutch study examined the cost case of using MRI and in bore MRI-guided biopsy as the primary initial diagnostic modality in the management of prostate cancer and found the approach to be nearly cost-equivalent to current management with a significant improvement in QALYs. A number of assumptions in this study may limit its generalizability including the low costs associated with multiparametric MRI (€300) and MRI-guided prostate biopsy (€800) (4). Another concern with the current models is that they assume that no biopsy is performed on men with negative imaging. The impact of "missed cancer" will need to be assessed in prospective studies. External to the issue of cost is that of value derived by the patient, especially in the indication of initial biopsy; even if an MRI-based initial evaluation of prostate cancer is non-cost effective it may still be desirable as approximately one third of ultrasound biopsies are upgraded when subsequently evaluated with MRI guidance (7).

Studies of mpMRI guided biopsy in men with prior negative ultrasound biopsy have shown an increased rate of detection of high grade tumors, especially in the anterior prostate, a region often poorly sampled in ultrasound-guided biopsy (28). A study from 2015 showed both cost savings in using MRI to inform repeat biopsy and that a large portion of repeat biopsies could be avoided (16). In patients undergoing mpMRI-guided biopsy after negative prior biopsy the possibility of avoiding systematic (non-targeted) biopsies as a cost saving measure has been raised. This approach should be used with caution as it appears that systematic biopsies still add value and detect some clinically relevant cancers in this setting (15). As MRI techniques continue to refine and MRI use in prostate cancer management grows, MRI before repeat prostate biopsy is likely to become increasingly common.

Three different cost analyses of prostate MRI used different costs for MRI. A study from a Dutch group used a cost of MRI at €345, an American study using medicare reimbursement rates of $524 and a Canadian study using hospital expense of $900 (16, 17, 28). The determination of baseline costs can result in significantly different conclusions especially if one considers using MRI in every patient with an elevated PSA. Such factors may limit the ultimate conclusion of a cost analysis to its nation of origin. In many healthcare environments, the limiting factor for MRI use may not be cost but availability (29).

The purest form of utilizing MRI information in prostate biopsy is performing multiparametric MRI and subsequent in-bore MRI-guided biopsy of suspicious lesions. While this approach demonstrates high quality performance characteristics (30), resource availability will likely limit its widespread use. An intermediate option is the use of MRI-ultrasound fusion hardware and software packages that allow the MRI data to be superimposed over live ultrasound images, guiding the provider during the biopsy. The utility of MRI-fusion software and hardware is itself a point of controversy. In theory a provider could review relevant MRI images and target a region of interest using ultrasound guidance, a practice used elsewhere in the body for the biopsy of metastases. This practice of viewing the MRI and targeting with ultrasound is generally referred to as "cognitive fusion" (31). The fusion approach involves use of software that overlays an MRI image on a "real-time" ultrasound image allowing assessment of the accuracy of the biopsy in relation to the MRI. A 2015 study in an ex vivo model showed greatly improved detection of relevant lesions using MRI machine-based fusion versus cognitive fusion (22), however a prospective, blinded in-human study failed to show a difference in cancer detection between the two modalities (21). Similar results were found in another in-human 2013 prospective study which found no difference in cancer detection between machine-based fusion and cognitive fusion (23).

Conclusions

mpMRI fusion biopsy is becoming the accepted method for diagnosing prostate cancer that allows the most cost/effective beneficial when done with proper instructions.

The costs (531,00 E + 40,00 - 120,00 E for fusion platform each patient) are a problem as the availability of mpMRI and of skilled uroradiologists, but we urologists have to be prepared to face this challenge, so the health system.

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