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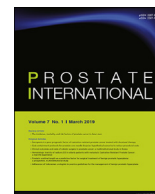
Original Article

Cost-containment protocols for prostate core needle biopsies: hypothetical scenarios to reduce procedural costs

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ABSTRACT

Background: In recent years, anatomic pathology laboratories have been struck by new revenue policies secondary to the Affordable Care Act. In particular, modifications to compensation for processing prostatic core needle biopsies (PCNBs) have led to important reimbursement cuts. Herein, we explore a hypothetical reduction in the costs for the processing of PCNBs using three simple, hypothetical methods while maintaining high-standard patient care.

Materials and methods: We determined the number of blocks and slides used per case on all PCNBs performed at our institution from August 2013 to September 2014 and calculated the total procedural cost for each case and for the total number of cases processed during the study period based on a published estimated procedural cost. We then estimated the procedural cost of three different proposed hypothetical scenarios that consisted in reducing the number of blocks used per case. A Student t test was used to assess the difference between real and hypothetical costs.

Results: A total of 4,406 paraffin blocks were used to process 363 PCNBs with a total annual procedural cost of \$26,303. By implementing any of the hypothetical scenarios, the annual procedural cost was significantly reduced; the reduction could potentially be as low as \$8,978 ($P < 0.0001$).

Conclusions: This study illustrates three hypothetical alternatives that could dramatically reduce the procedural costs of PCNBs while maintaining high-quality care. Implementation of these scenarios at a global scale could potentially have an impact on health-care cost in the USA of several millions of dollars per year.

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1. Introduction

Prostatic carcinoma (PCa) is the most commonly diagnosed cancer in males in the United States of America, accounting for one in four newly diagnosed cancers each year. In 2015, this number equated to approximately 220,800 new cases and 27,540 deaths.[1] Currently, the 10–12 prostate core needle biopsy (PCNB) sampling protocol is considered the standard of care for the diagnosis of PCa due to its higher cancer detection and lower false negative rates.[2] It also provides precise information for localized therapy and improves the correlation with Gleason grading.[3–5]

Several major changes have taken place since the Patient Protection and Affordable Care Act was signed into law on March 23, 2010. The Act directed the Centers for Medicare Services to revise high-volume medical services, including PCNBs, to adjust reimbursement fees. The most notorious example was a 52% reimbursement cut in the technical component of the 88305 Current Procedural Terminology (CPT) code, with a mild increase of 2% in the professional component. However, the total payment for 88305 suffered an overall reduction of 33%.[6] This represents a drop from \$69.78 to approximately \$33.70 per case coded as 88305. The consequences of these new policies could represent a loss of as high as \$460 million in revenue per year for some laboratories.[6–8]

Hence, we propose three hypothetical scenarios that could potentially help overcome these reimbursement cuts by implementing simple, rapid protocols, aimed to decrease procedural costs while maintaining high-standard patient care.

2. Materials and methods

2.1. Acquisition of data

Under an institutional review board, we retrieved and reviewed the pathology reports of all the PCNBs performed at our institution

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over a one-year period from August 2013 to September 2014. We generated a database including the demographic information, the histopathological diagnosis, the number of paraffin blocks and slides used per case, the site of the prostate samples, and the location and the grading of the carcinoma cases for further analysis.

2.2. Cost analysis

Our current active protocol for processing PCNBs is in accordance with the current consensus recommendations from the Association of Directors of Anatomic and Surgical Pathology, the College of American Pathologists and the International Society of Urological Pathology.[9] It recommends using one PCNB per container and per paraffin block. In addition, our institutional protocol includes the cut of deeper levels from each paraffin block and a total of two slides prepared per block; thus, a 12-PCNB case usually consists of 12 paraffin blocks and 24 slides. Based on published estimates by Buesa,[10] we calculated the procedural cost per case from grossing to slide preparation in a manual/automated laboratory and included the estimated cost to cut and stain additional sections of the same paraffin block to account for the deeper sections taken from each block. The results were used to estimate the total procedural cost per case for the one-year study period using the actual numbers of supplies and cases at our institution, and numbers were obtained based on the three different hypothetical scenarios (see below).

2.3. Statistical analysis

Results are reported in absolute and relative frequencies with means and standard deviation or medians and ranges, accordingly. The difference in the cost of the actual scenario at our institution and the three hypothetical scenarios was assessed using a Student t test.

3. Results

3.1. Sample description

The pathology reports of 363 PCNBs belonging to 355 men (median age: 65, interval: 43–90 years) were reviewed and included in the study. A total of 149 (41%) cases were diagnosed with PCa. The 10–12 core needle biopsy protocol was performed in 167 (46%) cases. Most of the sites sampled yielded benign prostatic tissue (80%), followed by Gleason 6 adenocarcinoma/Grade Group 1 (5.5%), Gleason 7/Grade Groups 2 and 3 (4.4%), Gleason 8/Grade Group 4 (1.4%), Gleason 9/Grade Group 5 (1.1%), and Gleason 10/Grade Group 5 (0.3%). High-grade prostatic intraepithelial neoplasm was observed in 28 (0.7%) of the sampled sites, and 68 (1.6%) sites were deemed equivocal for malignancy. The tissue obtained from three sites (<1%) was too small to be interpreted. The most frequent biopsy site was the left lateral base (98.9%, n = 359/363) followed by the left lateral mid (97.8%, n = 355/363); however, PCa was more frequently diagnosed on the right side of the prostate without reaching a statistical significance (P = 0.94). Table 1 summarizes the distribution of the 149 positive cases according to Gleason score and anatomical location. Cancer involvement was evenly distributed throughout the 12 anatomic locations included in the 10–12 biopsy protocol. PCa was primarily diagnosed in individuals aged between 60 and 80 years, whereas those <50 years were more rarely affected.

3.2. Cost analysis of the study period

Based on the gross description in the pathology reports and our current protocol, we calculated the total number of blocks used per case (n = 4,406) and the total number of slides required for each case (n = 8,812) that were used during the study period. The median number of blocks and slides used per case was 12 (2–24) and 24 (4–48), respectively. We then used a published estimate[10] of $4.71 dollars for each case to calculate the procedural cost per case, as well as the total expenditure over the study period, from grossing to slide preparation in a manual/automated laboratory and a cost of $1.26 for cutting additional deeper sections.[10] The total procedural cost for the one-year study period totaled $26,303.82. The average procedural cost per case was approximately $72.46 (±15.25). Extra costs derived from additional deeper cuts or immunohistochemistry were not included in the calculation.

We then explored the following three possibilities to try to reduce the procedural costs in the histopathological laboratories: 1) embedding two PCNBs per paraffin block, 2) embedding three PCNBs per paraffin block following a "sequential" approach, and 3) embedding three PCNBs per paraffin following a "schematic" approach. In addition, we calculated the cost of including all six PCNBs from the right side and all PCNBs from the left in two separate cassettes. Although this practice is strongly discouraged, some institutions continue to process PCNBs using this unfavorable methodology.[9,11,12] Table 2 summarizes the amount of consumables (slides and paraffin blocks) and the hypothetical procedural cost per case over the entire study period in all different scenarios compared with the actual expenses.

3.3. Two PCNBs per paraffin block

According to this hypothetical scenario, each paraffin block would contain two PCNBs, one of which would be inked. By implementing this scheme, the number of blocks would be reduced to 2,225, and approximately 4,450 slides would be generated. In contrast to the actual cost, the total procedural cost would be reduced to $13,283.25, and the average procedural cost per case would be reduced to $36.6 (±7.5). This would represent nearly a

Table 1
Distribution of positive cases according to Gleason score and anatomical location.

Score	LLB	LLM	LLA	LB	LM	LA	RA	RM	RB	RLA	RLM	RLB	Total
PIN-HG	3	1	3	3	1	4	2	1	3	4	3	0	28
Gleason 6	27	22	22	12	21	21	22	17	19	13	21	22	239
Gleason 7	19	14	16	13	15	16	15	21	14	19	15	17	194
Gleason 8	6	4	6	6	2	3	5	5	5	6	6	7	61
Gleason 9	3	5	3	3	4	4	7	5	3	2	4	6	49
Gleason 10	1	1	2	1	1	1	0	0	1	2	1	1	12
Total	59	47	52	38	44	49	51	49	45	46	50	53	583
	Left (289)						Right (294)						

LA, left apex; LB, left base; LM, left middle; LLA, left lateral apex; LLB, left lateral base, LLM, left lateral middle; PIN-HG, prostatic intraepithelial neoplasia-high grade; RA, right apex; RB, right base; RM, right middle; RLA, right lateral apex; RLB, right lateral base; RLM, right lateral middle.

Table 2
Consumables, average, and total procedural costs per case and for the study period of the real and hypothetical scenarios.

Supplies/Cost	1 PCNB *real*	2 PCNB n	3 PCNB *schematic*	3 PCNB *sequential*	6 PCNB	*P*
			Per block			
Blocks (n)	4,406	2,225	1,759	1,469	1,033	<0.001
Slides (n)	8,812	4,450	3,518	3,008	2,066	<0.001
Average cost per case ($, ±)	72.5 (15.2)	36.6 (7.5)	29 (9)	24.7 (5.4)	17 (8.9)	<0.001
Total cost ($)	26,303.82	13,283.25	10,501.23	8,978.88	6,167	<0.001

PCNB, prostatic core needle biopsy.

50% reduction compared with our currently practiced protocol for PCNBs ($P < 0.001$).

3.4. Three PCNBs per paraffin block—sequential model

This hypothetical scenario is similar to the previous one but involves submitting three PCNBs per cassette in the order of their submission, even if a specific biopsy site is not sampled. Two PCNBs would be inked in two different colors, and the biopsy in the middle
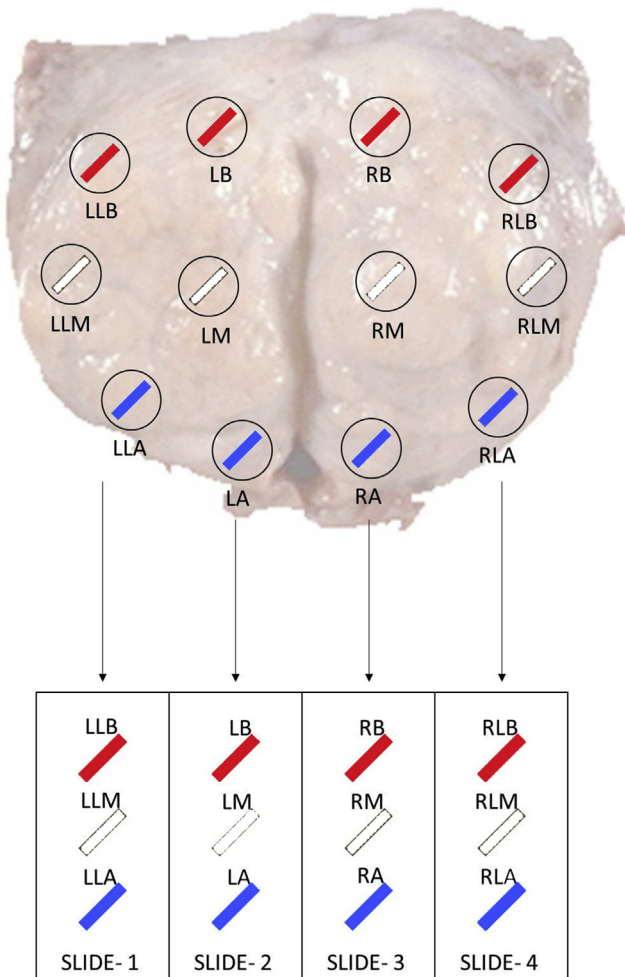

Fig. 1. Schematic model for submitting three PCNBs per paraffin block. This figure illustrates the 12 anatomic locations commonly sampled in prostatic biopsies. Each biopsy has a specific location and is inked and submitted in a paraffin block based on this scheme. If any of the biopsy sites is not sampled, then that spot(s) is not used; therefore, all cases with 4 to 12 biopsies will be placed in four paraffin blocks. LLA, left lateral apex; LLB, left lateral base, LLM, left lateral middle; PCNB, prostatic core needle biopsy; RLA, right lateral apex; RLB, right lateral base; RLM, right lateral middle.

would not be inked, to avoid mixing of colors[13] (e.g., left lateral base, left lateral middle, left lateral apex in one cassette with blue, no ink, and red ink, respectively). With this protocol, cases containing one to three biopsies will have one paraffin block and two slides, cases with four to six biopsies will have two paraffin blocks and four slides, and so forth. Therefore, most of the cases following the 10−12 biopsy protocol would be processed in three to four paraffin blocks and six to eight slides. Each additional PCNB can be inked accordingly and sequentially submitted; for example, a 24-PCNB case could potentially be submitted in eight paraffin blocks and 16 slides. The total procedural cost by using this method would be reduced to $8,979.88, and the average procedural cost per case would be reduced to $24.73 (±5.4). This scenario yields the maximum amount of savings (up to 65%). However, it could generate some confusion at the time of grossing and during sign-out.

3.5. Three PCNBs per paraffin block—schematic model (preferred)

Of the 363 cases, we focused only on 232 (35%) cases that encompassed between 4 and 12 PCNBs per case. We believe that cases with less than four PCNBs can be processed by embedding one PCNB per cassette, without affecting the overall cost. For cases with more than 12 PCNBs, any additional biopsy can be embedded separately in one block. By restricting the use of this model to cases with 4 to 12 PCNBs, three biopsies can be submitted in each block, and every alternate biopsy can be inked as previously described (Fig. 1). The difference relies in the fact that if a specific site were not sampled, then the corresponding spot would be left empty on the block and on the slide. This schematic model will be easy to follow by pathologist assistants and will help to reduce mistakes at the time of grossing and sign-out. Based on specific colors and their corresponding location, pathologist should be easily able to orient each sample at the time of sign-out because regardless of the number of PCNBs submitted, each biopsy will have a specific location. The estimated total procedural cost of this model was calculated to be $10,501.23 with an average procedural cost per case of $29 (±9). We prefer this method because it can potentially avoid confusion and facilitate convenient grossing and interpretation.

4. Discussion

During the past few years, legislation on the quality of healthcare, cost containment, patient safety, and satisfaction has steadily increased, indirectly impacting overall health-care costs. Currently, there is no consensus on the number of PCNBs that can be safely placed in a container or a paraffin block for adequate pathological analysis.[9,11] Available data suggest that processing multiple PCNBs in a single container or paraffin block compromises pathological evaluation.[9,11,12] It has been reported that there is a potential risk of losing as much as 40% of tissue when submitting more than two PCNBs per paraffin block.[11,12,14] However, other authors have found

that the yield of cancer is similar with the submission of one to three PCNBs per cassette.[11,15] Moreover, when using the appropriate type of cassettes, one could potentially include as many as six PCNBs per cassette.[16] The limiting factor in bundling multiple PCNBs for histologic processing appears to be the impending entanglement of the biopsies[16] and the technical processing of the samples. Nevertheless, because this is an operator-dependent process, a dedicated experienced histotechnologist could potentially resolve this issue.[13,16] At our institution, for example, we have a dedicated histotechnologist who processes kidney core needle biopsies at two microns and is able to include more than two cores in the same paraffin block with optimal results. In addition to allocating experienced personnel to the process, placing PCNBs between two nylon meshes before fixation to avoid tissue entangling and fragmentation has shown to decrease entanglement and increase the frequency of cancer diagnosis.[17]

By implementing the new Patient Protection and Affordable Care Act fee schedule, the reimbursement for the technical component for the CPT code 88305 used for PCNBs almost halved. In addition, the number of containers used also has an important impact on revenue. Firoozi et al[18] recently published one alternative to reduce the number of containers using a similar model of inking and submitting three PCNBs per container at the time of biopsy before sending the samples to the histology laboratory. Although we did not include this approach in our cost analysis, the addition of this step before the samples are delivered to the histology lab, coupled with any of the methods described in this study, could have the largest impact on reducing costs.

The limitations of the present study include the hypothetical nature of the scenarios; actual implementation should be undertaken to determine the real costs and additional hurdles and benefits that have not been studied or foreseen. The costs were based on a published estimate that did not include adjustments for inflation throughout the years; hence, pricing might vary slightly. Additional costs, such as the processing time, storage space, grossing time, other supplies, and pathologists' time to review slides, should be taken into consideration at the time of implementation. We did not directly analyze the impact of decreasing the time that each pathologist would take to review a case. However, we believe that it would be substantial. The steady increase in the number of PCNBs performed each year will also have a tremendous impact not only in costs but also in the transportation, reviewing, and archiving of paraffin blocks and slides; hence, a cost-effective solution is highly desirable.

In summary, reimbursement cuts are here to stay, and quality of healthcare, cost containment, and patient safety and satisfaction will play an even more important role in the years to come. Attempts focused on cost containment to overcome reimbursement cuts have been proposed[2]. In the present study, we analyzed the potential impact on decreasing procedural costs that could be achieved by modifying the grossing of PCNBs. Any of the proposed alternatives could potentially help to reduce a portion of healthcare costs in the United States of America, in the range of hundreds of thousands to several millions of dollars per year.

Conflicts of interest

All authors have no conflict of interest to declare.

Appendix A. Supplementary data

Supplementary data related to this article can be found at https://doi.org/10.1016/j.prnil.2018.02.001.

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