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Review Article

Variables Affecting the Histological Quality of Prostate Core Biopsy Samples in Cancer Detection

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Abstract

The examination of the prostate biopsy procedure is essential in the optimization of the diagnostic pathway of such a prevalent affliction as prostate cancer among men worldwide. With the core needle biopsy being the standard of care for the diagnosis of prostate cancer, the ability to obtain quality core samples is directly related to patient treatment and diagnostic reliability. Needle deflection and dynamic tissue deformation are two chief sources of unrepresentative samples outside of human error. To assess how these factors affect overall histological sample quality and what variables influence deflection and deformation, a review of related literature was conducted. A literature search using keywords [(core prostate) OR (prostate)] AND [(biopsy) OR (needle)] AND [(histological) OR (fragmentation) OR (deflection) OR (deformation)] AND [(factors) OR (rate) OR (quality)]. The resulting articles were analysed for relevance of factors influencing histological sample quality. The objective of this review was to analyse trends in the literature and comprise a comprehensive analysis regarding the factors that positively and negatively affect the final histological quality of the core specimens. The results highlighted the velocity of needle insertion into the soft tissue as a variable affecting dynamic deformation, and the geometry of the bevelled biopsy needle tip combined with the application of a biopsy template impacting the deviation of the needle from the linear target. Friction forces also significantly influence the final product as related to these factors. This literature study highlights the crucial parameters of the biopsy procedure and provides for a basis to discuss the improvements to the system and its external components to improve overall patient care. This suggests further investigation of these factors through their manipulation in controlled environments is necessary to improve the effectiveness of the biopsy procedure.

INTRODUCTION

The normal prostate is a 3 cm long, 4cm wide, and 2cm deep (anteroposterior diameter) inverted cone-shape accessory gland of the male reproductive organ (approximately 30g) that lies in the pelvic cavity below the urinary bladder and above the elevator any muscle (pelvic floor), behind the pubic syphilis and in front of the rectum through which it can be palpated by rectal examination. Prostate historically has an anterior (isthmus) and a posterior lobe, a middle (median) lobe, and two lateral lobes, although clinical classification may be a little different [1-3]. Prostate is a fibro muscular (1/3) and glandular (2/3) tissue. The glands are distributed in three zones including the transitional zone that contains about 5% of the prostatic volume and surrounds the prostatic urethra, the central zone that comprises 25% of the prostatic volume and surrounds the transitional zone, and the peripheral zone where 80% of the prostate cancers occur, surrounds the central zone and consists of 75% of the volume of the prostate [1].

In 2021, prostate cancer represented the most prevalent cancer type among males, accounting for 26% of all cancer diagnoses. In the United States, 1 in 8 males were expected to be diagnosed with prostate cancer, and a mortality rate of 11% ranks it as the second-highest cause of cancer death in males [4]. The key factors in assessing the risk of prostate cancer development include age and family history; survival rates of men with prostate cancer are relatively high, with only a 2.5% lifetime risk of dying due to the disease, but the median age of death due to prostate cancer is 80 years old. These factors suggest that men aged 55 to 69 years should undergo periodic screening for prostate cancer [5].

Clinical screening for prostate cancer begins with an analysis of the level of prostate- specific antigen (PSA) in the blood. PSA is a serine-protease that is naturally produced by epithelial cells lining the prostate and is an essential protein in semen, and is normally found in low levels in the blood. Elevated concentrations of PSA (measured in nanograms per millilitre, ng/ml) act as a serum marker for cancerous lesions [6].

Conventional clinical guidelines indicate that a serum PSA concentration of above 4ng/ml warrants further analysis; however the risk factors of the patient may suggest a cut-off of 3ng/ml or 2.5ng/ml. The lack of standardization in this diagnostic method is due to the many possible physiological conditions that may elevate serum PSA other than cancer, including prostate inflammation (prostatitis), benign prostatic hyperplasia, and even ejaculation [5]. As a result, repeated screening and early detection of elevated PSA reduces prostate cancer mortality by over 20%, but the risk of false positive results is fairly significant [7,8]. One trial demonstrated that over a 10-year period, 15% of men who were screened every 2 to 4 years experienced at least one false-positive result for prostate cancer [9]. A secondary, less accurate method for diagnosing prostate cancer is the Digital rectal Exam (DRE), in which a physician will manually examine the posterior region of the prostate through the rectum to feel for a solid mass.

PROSTATE CORE BIOPSY

With the guidance of the physician, the results of a PSA or DRE screening may be followed by a prostate biopsy. A prostate biopsy is the only method of accurately determining if a patient has a cancerous lesion or not. A tissue biopsy mechanism generally contains a bevelled needle with an indentation for an isolated specimen, and a deployment mechanism (spring-loaded, manual, etc.) that inserts a cutting sheath over the bevelled needle. The tissue cutting system is separated into two phases: an initial phase in which needle force accumulates to the amount required to separate the tissue, and a secondary phase where needle force stabilizes once the tissue has been separated [10]. The varieties of forces that act on the needle in each stage induce deflection and other sources of error that ultimately determine the accuracy and quality of the biopsy sample. There are two major variations of core prostate biopsies that are currently routinely performed, including the trans rectal and transperineal (Trans gluteal is performed to a lesser extent), which differ in their point of insertion.

Tran's rectal biopsies are maneuverer within the rectum before penetrating the rectal wall, while transperineal biopsies are done through superficial intervention. The trans rectal ultrasound-guided (TRUS) biopsy may miss some anatomical portions of the prostate (favours probing of the posterior region) while transperineal biopsies favour the anterior prostate [11].

TRUS procedures are more practical, since only a local anaesthetic is required and can be completed within an office setting; while the perinea approach can be performed under general anaesthesia, an increasing number of physicians are performing transperineal procedures under the same conditions as TRUS [12]. Patient movement during TRUS biopsies can have a negative impact on biopsy results, representing an additional drawback that is avoided if the transperineal approach under general anaesthesia is utilized. The efficiency of TRUS biopsies are paired with an increased likelihood to develop infection due to non-sterility and complications ranging from moderate to severe rectal haemorrhaging compared to the more sterile transperineal approach [13].

Recent biopsy mechanisms have been improved from the original sextant form through technological advances, better understanding of zonally anatomy of the prostate (allowing for consideration of lateral lesions), and computer modelling of localized prostate cancer [14]. Robot-assisted TRUS has been found to increase biopsy precision, and the more accurate needle targeting has the potential to increase the detection of clinically significant prostate cancer per procedure. The use of prostate magnetic resonance imaging (MRI) in the risk stratification, diagnosis, and treatment pathway of men with prostate cancer is expanding as well, providing more accurate needle insertion into the cancerous lesion and a more reliable diagnostic pathway for potential cancer patients [15]. Incorporating multipara metric MRI into the diagnostic pathway as an initial test prior to prostate biopsy may reduce the proportion of men having unnecessary biopsies, improve the detection of prostate cancer, and increase the cost-effectiveness of the prostate cancer diagnostic and therapeutic pathways [16]. The inherent direct relationship between the number of biopsy procedures performed and the complications experienced by the patient suggest the potential for the accuracy of MRI to play a role in developing a more rapid diagnosis and treatment implementation.

ANALYSIS OF CORE BIOPSY SAMPLES

Core biopsy samples are analysed by pathologists to determine the clinical application of the specimen. For the evaluation to be accurate, the biopsy specimen must have certain histological characteristics that qualify it as an appropriate model. The specimens are produced as cylindrical cores of the target tissue resulting from the shape of the cutting sheath. Primarily, the biopsy sample should have been taken from the region of interest (i.e. a lesion or growth). The specificity of the sample and the false negative rate of cancer diagnosis that it produces are largely dependent on the volume of the sampled tissue [17]. Since this is correlated to its length, a longer biopsy core with greater diameter is a desirable characteristic.

Fragmentation of the biopsy sample is also a concern, since no conclusive data can be drawn about the physiology of the region.

When an optimal sample is obtained, it will be analysed on a standardized scale called the Gleason Score, a grading system from 1 to 5 used to categorize the progression of the cancer within the tissue [18] (Figure 1).

Deflection of the needle and dynamic tissue deformation are two potential sources of error during the biopsy procedure that needs to be accounted for. Tissue deformation includes three cases: the displacement of the tissue, relative sliding of multi-layer soft tissue and motions of the organs. The amount of gaps within soft tissue makes it easily compressible, causing the volume to change with deformation [19]. Deformation of the tissue results from the force of the rigid needle at the focal point of the target before penetration, resulting in movement in the tissue layers and potential movement of the target. Innovations including model-

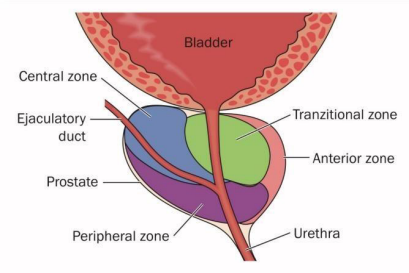

Figure 1 Lobes of the prostate gland, transperineal biopsies are biased towards anterior zone of the prostate, while Tran's rectal biopsies tend to evade this region.

based path planning and robotic steering of the needle have been proposed, but are largely inconsistent due to the inhomogeneity of the human tissue layers [20]. Needle deflection involves the needle deviating from the linear trajectory of the needle and instead following a curved path, caused by the bevelled needle tip and the flexibility of the body [21]. A suggested solution to this phenomenon involves rotating the needle to continuously redirect the deflection path, but histological analysis suggests this technique invokes tissue damage and expansion of the entry point [22].

METHODOLOGY

This literature review was conducted using a compilation of relevant research articles sourced using PubMed and Google Scholar. The preliminary search keywords included words related to the procedure and target location of interest (core prostate and prostate), words to isolate either the procedure or the mechanism (biopsy or needle), words indicating the measures or variables of interest (histological, fragmentation, deflection, and deformation), and additional terms to filter for analysis (factors, rate, and sample quality). The search was thus conducted using the keywords [(core prostate) OR (prostate)] AND [(biopsy) OR (needle)] AND [(histological) OR (fragmentation) OR (deflection) OR (deformation)] AND (factors) OR (rate) OR (sample quality). The relevance of the article was the major determinant in its selection. The search involved exclusion criteria such that the study had to employ a clinical trial or preclinical model, the language of publication was restricted to English, and publication date had to be listed on or after 2000. Impact factor of the publishing journal and number of citations were not considered in the selection of the papers. Articles investigating topics apart from core biopsies and histology were omitted from the literature review (Figure 2). The distribution of the articles based on study type and the variable that was analyzed may be found in Figure 3.

RESULTS

Overall, the search yielded 69 results through the PubMed and Google Scholar search engines. A total of 42 were excluded based on the described exclusion criteria, and the remaining 27 articles produced 13 results after irrelevant papers were removed. The distribution of the articles based on study type and the variable that was analysed may be found in Table 1. The data of these articles were considered in the following discussion.

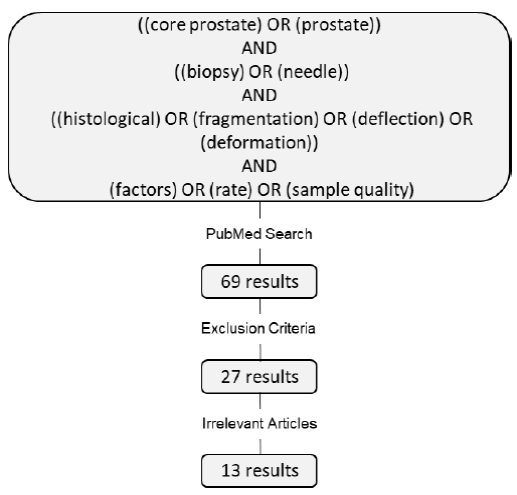

Figure 2 Flowchart of the search method, showing the progressive filtration of articles using the inclusion (key terms) and exclusion criteria.

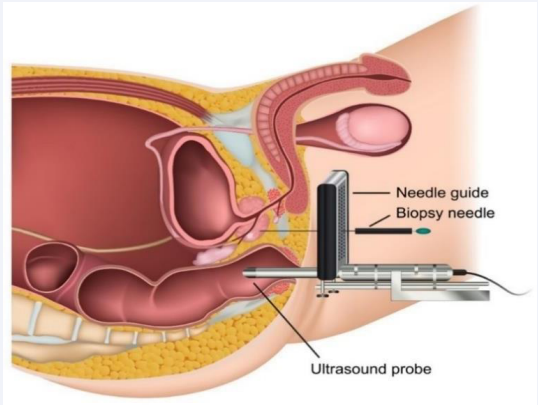

Figure 2 Flowchart of the search method, showing the progressive filtration of articles using the inclusion (key terms) and exclusion criteria.

Table 1: Comparison of the search results by variable evaluated and study type, *ex-vivo*, **animal model *in-vivo*.

Subgroups	References
Variable Evaluated	
External equipment	27, 28, 29
Fragmentation rate	25
Needle tip geometry and dimensions	24, 26, 31, 32
Needle deflection	27, 23
Insertion velocity	10, 19, 30
Internal surface polishing	17
Study Type	
Clinical models	25, 26, 27, 29, 32,
Preclinical models	10*, 17, 19, 23*, 24*, 28, 30**, 31*

DISCUSSION

The factors affecting the histological quality of a core prostate biopsy sample can be categorized into variables affecting the location accuracy of needle insertion and variables affecting needle insertion velocity as it relates to tissue deformation.

Location Accuracy

The geometry of the needle tip is the most superficial aspect affecting the location accuracy of needle insertion into soft tissue. Core prostate biopsies are often performed using a true-cut biopsy needle with a single bevel and a groove for the sample surrounded by a hollow cannula for sampling. Despite advances in imaging guided systems, including MRI-ultrasound fusion targeted biopsies (MRF-TB), deflection induced by these single-bevel needles causes variance between the target location and final sampling location [23].

Ultrasound-guided techniques, including TRUS core biopsies, experience limitations in this area as well, since ultrasound probes inserted through the rectum may shift the positioning of the prostate or compress it.

The single-bevel needles in current hand- held biopsy devices often deflect significantly during needle insertion, causing variance in the targeted and actual locations of the sampled tissue. This variance can lead to inaccurate sampling and false-negative results [24]. Studies have shown that the inclusion of multiple bevel tips can generate opposing forces that balance the arc motion of the needle within the tissue. However, currently proposed multi-bevel designs suffer from altering the tissue separation point, and thus reducing tissue sampling length and potentially compromising the cancer diagnostic accuracy of the sample [23]. A full-core or side-notch biopsy needle system represents another variable affecting the technique that was used to extract the sample. A randomized trial comparing the histopathological quality and physical features of biopsy cores indicated that the full core system produced significantly higher quality samples than the side notch system, favouring this layout to increase sample length and decrease fragmentation rate [25]. Even within multi-bevel needle systems, there remains a variation in sampling ability. One study demonstrated that Fork-tipped and Fran seen geometries recorded producing better overall histological quality than reverse-bevel and Menuhin tips, evidently displaying an inconsistency in the various multi-bevel needle designs [26].

Location accuracy in core biopsy insertion is also dependent on the interaction between the biopsy template and the needle insertion mechanism. Application of a grid or template is only utilized in transperineal biopsy approaches and cannot be used in Tran's rectal biopsies. The general consensus according to clinical trials of the utilization of a biopsy template remains controversial. In core prostate biopsies, following a template could better ensure uniform and well distributed sampling of the prostate compared to the traditional freehand biopsy approach, possibly decreasing the chance of false-negative biopsy [27]. However, the application of a grid or template has also been shown to be susceptible to error; the increased friction associated with a smaller grid clearance does have a drawback in the reduction of the insertion velocity of the needle. This suggests an increase in tissue deformation, but underlying improvement in precision and accuracy of needle insertion is generally present regardless of the insertion speed [28]. The tightness of the stabilizing agent to the needle affects the correlation of the grid coordinates and degrees of rotation during needle insertion, potentially allowing technical and equipment-associated error.

This suggests that technique remains critical even when using a template for insertion, and therefore does not necessarily imply reproducible needle placement [29]. An additional drawback to the application of an external grid is the limitation it presents to the physician in the insertion of the needle, since guides are stable and may restrict the needle from being directed to a location of interest.

Insertion Velocity

The rate at which the needle is inserted into the target tissue has a significant effect on the final histological quality of the sample, mainly through the effect of acceleration on dynamic soft tissue deformation. The results of one experimental analysis showed that maximum tissue deformation occurs upon insertion of the needle, obscuring the target lesion at the point in which the tissue and needle made contact. Past that point, an increase in insertion velocity leads to a decrease in deformation due to the generation of kinetic and viscous energies. This produces a decrease in targeting error and a more histologically valuable biopsy sample [19]. During insertion of the needle, the contact between the surface of the needle and the tissue creates friction stresses.

Average friction stress along the needle- tissue interface has been shown to decrease with increasing insertion speed [30]. Increased needle insertion velocity minimizes the force required in the first phase of tissue- cutting procedure, while minimizing tissue displacement in phase two. High velocity needle insertion also yields a greater improved histological sample quality by producing biopsy cores with a greater mean molecular weight [10].

The characteristics of the biopsy needle according to its manufacturing are another source of variability in obtaining quality biopsy core samples. One aspect of this is the design of the grooves and cannulas to accommodate a greater length of tissue sample. One study which compared the cancer detection rates of 19mm and 29mm cutting lengths concluded that taking the longer cores led to an improved cancer detection rate of nearly 20% [31]. The process of developing a stainless-steel needle involves running a tube through a mandrel and a die to control the inner and outer diameters of needle, respectively. With the rise of a clinical preference for smaller diameter needles (i.e.18-guage) afforded by decreased trauma to the patient, not only are a greater number of passes required to obtain a sufficient amount of tissue for analysis, but the commercial method of using a mandrel is not applicable, so the inner surface is often less smooth than larger diameter needles, negatively impacting sample quality. The development of polishing techniques for 18-guage core biopsy needles has been shown to improve histological sample quality and decrease fragmentation due to a decreased insertion friction force [17]. Aside from interior

polishing, exterior sharpening of the needles using a trocar have been shown to be superior to industry standard needles in histological sample quality, targeting the planned position, and performing the biopsy in the proper time [32].

FUTURE DISCUSSION

The nature of this analysis as a literature- based review of the factors affecting biopsy sample quality does have the limitation of potentially not encompassing every detail associated with the system. However, many of the major factors were highlighted and narrowed down to fit the scope of this text. The structure of this analysis implies its potential as a reference to the general core biopsy procedure and experimentation with the variables mentioned. The holistic approach of this study in its aim to identify the various factors affecting the biopsy procedure makes it functional for adaptation to clinical, research, or commercial settings relating to core prostate biopsies. Future work may optimize the parameters outlined in this study to improve the current biopsy mechanism or system of imaging and manufacturing relating to biopsy needles.

CONCLUSIONS

In this paper, an analysis of the variables influencing the final histological quality of core prostate biopsy samples in cancer detection using the published literature was developed. The results show that the factors affecting the overall quality of a core biopsy outside of human error include those impacting the deformation of soft tissue and the deflection of the needle upon insertion. These categories present a lasting influence on the desirable characteristics of a biopsy sample, including high mean molecular weight, low rate of fragmentation, and sampling from the target lesion.

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