

Needle Size and Transrectal Prostate Biopsy: A Prospective Comparative Study of 16 Gauge Versus 18 Gauge Needles

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ABSTRACT

Background: The diagnosis of carcinoma of the prostate involves prostate biopsy and histopathological confirmation. While many urologists perform prostate biopsy using 18 gauge (18G) needles, larger 16 gauge (16G) needles have the potential of increasing the diagnostic yield from biopsy, which may in turn improve cancer detection rate.

Objectives: The aim of this study was to evaluate the outcome of transrectal prostate biopsy with 16G tru-cut biopsy needle in comparison with 18G trucut biopsy needle.

Methods: This was a randomized comparative study carried out at the University of Benin Teaching Hospital (UBTH), over a one-year period. Ninety patients who underwent biopsy were divided into two groups with 45 patients in each group. Group one had biopsy using size 16G needles, while group two had biopsy using 18G needles. Twelve cores were taken per patient. All patients were given antibiotics, beginning 24 hours before the procedure and continued for 5 days post biopsy.

Results: Ninety patients underwent biopsy. Of the 45 patients who underwent biopsy using the 16G needles, 22 (52.4%) diagnosed with adenocarcinoma of the prostate. While in the 18G needle biopsy group, 20 (47.6%) were adenocarcinomas thereby showing an improvement in cancer detection of 4.4%, in favour of the 16G group. Patients that had biopsy using 16G needles reported slightly more pain during and after the procedure, than those in the 18G group. The commonest complication recorded was haematuria, seen in an equal number of patients in both groups.

Conclusion: Transrectal prostate biopsy using 16G needle results in better quality of tissues, without increasing patient discomfort or other complications.

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INTRODUCTION

Prostate biopsy has progressed over the past century, from an era of significant morbidity, to the point where at present, it can be performed in a clinical office setting with low morbidity. Major complications are now uncommon, and it is now one of the most commonly performed procedure by urologists worldwide (Nieder & Soloway, 2008). Hand held high resolution ultrasound probes and spring loaded needles have allowed systematic and

directed trans-rectal ultrasound (TRUS) guided biopsies. However, in countries with limited resources, this facility is not readily available. Regular use is thus made of digitally guided trans-rectal biopsy of the prostate (Hodge et al., 1989; Onuora et al., 2004; Shittu & Kamara, 2002).

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Digitally guided trans-rectal biopsy is well tolerated and has minimal complications, with a high sensitivity for diagnosing prostate cancer, when carried out properly (Hodge et al., 1989; Onuora et al., 2004; Shittu & Kamara, 2002).

A few studies have examined the importance of core size in prostate biopsy. Inal et al. in a study comparing 16G and 18G needles noted the samples taken using the larger caliber 16 gauge needle were of better quality and quantity, but there was no statistically significant difference in the cancer detection rate (Inal et al., 2008). McCormack et al. also compared 16 gauge and 18 gauge needles in prostate biopsy, but noted no statistically significant difference in cancer detection rates (McCormack et al. 2012).

In our center (UBTH), 18G needles are used for digitally guided trans-rectal biopsy in the diagnosis of prostate cancer in those with suspicious digital rectal examination (DRE), elevated serum prostate specific antigen (PSA), or both.

There have however been reports of inadequate tissue samples for histopathologic analysis, and some reports of benign hyperplasia in patients with suspicious DRE, and elevated serum PSA, situations which call for repeat biopsy. This poses both physical and financial stress on the patients with some defaulting on clinic visits. Methods for improving the accuracy of prostate biopsy are therefore desirable.

The dilemma between higher sensitivity versus higher morbidity (which in this case are represented by the amount of tissue to be examined together with a degree of homogenous sampling of the prostate and complications respectively) has been going on since the sextant biopsy scheme was first described by Hodge et al. (1989). Although more biopsy cores assure higher sensitivity, higher complication rates and poorer patient comfort are well known major associated drawbacks (Helbich et al., 1998). The sensitivity could be improved by increasing the amount of sampled tissue, either by increasing the number of cores, or by increasing the amount of tissue per core (Iczkowski et al., 2002; Ficarra et al., 2006). Ten to twelve biopsy cores have thus been recommended to increase the number of cores and thus improve the sensitivity (Scattoni et al., 2002). Similarly, the quality of the samples could be improved by using needles with longer or larger calibers, thus increasing the amount of tissue per core biopsy (Ficarra et al., 2006).

Eighteen gauge trucut needles are commonly used as the standard biopsy equipment in most centers (Inal et al., 2008). Sixteen and 18G needles both have the same core length of 17mm; however,

owing to the difference in the diameter of the two needles, the core volume of an 18G needle is 12.18mm³, whereas that of a 16G needle is 20.25mm³ which in effect means that the core volume of 16G needle is 1.7 times larger than the 18G, with a theoretical increase of about 70% in core volume (Inal et al., 2008). Hence, it may be argued that the use of 16G needle may improve specimen quantity and quality by acquiring more undistorted prostatic tissue per core, which in turn may facilitate better pathological examination (Inal et al., 2008) and improved cancer detection. Most of the cancers detected in Nigeria are well differentiated adenocarcinomas (Onuigbo, 1984). The use of larger caliber needles has been shown to markedly improve specimen quantity and cancer detection in breast biopsies. In a study by Helbich et al comparing the quality and quantity of tissue harvested from breast biopsy specimen when using 14-, 16- and 18G needles, they found that tissues obtained with the larger caliber needles were significantly larger; 14G-13.14mm²; 16G-9.6mm²; 18G-6.41mm²; and accordingly scored significantly better in cancer detection (Helbich et al., 1998).

Nath et al. also supported this finding in their study comparing samples obtained with 14-, 16-, and 18G needles in breast biopsy specimens where they studied 57 surgically removed mass lesions of the breast with each needle size (Nath et al., 1995). They found the sensitivity for diagnoses of all 26 malignant cases was 100%, 92%, and 65%, for biopsy samples obtained with the 14-, 16-, and 18-gauge needles respectively. Hence, they concluded that the larger caliber needles provided the most accurate diagnosis which correlated with the diagnosis made with the surgical excision biopsy technique (Nath et al., 1995).

Few studies have examined the importance of core length in prostate cancer. However there has been rising interest in defining more accurate prostate biopsy schemes in order to improve prostate cancer detection rates (Cicione et al., 2012). Since the beginning of the last century trans-rectal ultrasound needle guided biopsy of the prostate has been used to diagnose prostate cancer and it is considered to be an accurate method for obtaining prostatic tissue for histopathologic evaluation (Borley & Feneley, 2009). Nevertheless, the most efficient scheme with optimal number and location of cores has not yet been defined (Cicione et al., 2012).

Thus, the purpose of this study is to ascertain if cancer detection rate is improved with the use of larger caliber 16G needles as opposed to 18G needles, and to determine its impact on post

biopsy complications. It is expected that this may also help to reduce the need for repeat biopsies.

METHODS AND MATERIALS

Study area and study setting

The study was carried out in the Urology unit, of the Department of Surgery, UBTH, Benin-City, Edo State. The hospital is a tertiary institution that renders specialist care in various fields of Medicine. It has a well-established Urology Unit and serves as a major referral center for patients in Edo state and its environs. It is a 600 bed hospital, with various facilities. The Urology Unit renders diagnostic and therapeutic services which include lower urinary tract endourologic services, andrology, reconstructive urology, uro-oncology, urogynaecology, and other open urologic surgical services. There are also histopathology and radio-oncology services available in the hospital.

Study design & study participants

This is a prospective randomized comparative study, carried out at the UBTH over a one year period. Patients studied included those with clinical suspicion of prostate cancer, following initial evaluation at the urology out-patient clinic. These patients had elevated PSA or abnormal DRE, or both. The study was carried out over a 12 month period from August 2015 to July 2016.

Sample size determination

An estimated sample size for the study was calculated using sample size calculation formula for comparative studies (Araoye, 2004). The assumption was that both groups will have the same number of patients: $n_1 = n_2$

Sample size was calculated using the formula $N = \frac{2z^2pq}{d^2}$

N = Estimated sample size

Z = Standard normal deviation (from standard deviation table) at 95% confidence level = 1.96.

P = cancer proportion detected from previous study (Inal et al., 2008) = 24% (0.24)

q = 1 - p = 0.76

d = degree of precision, with an observed difference assumed at 20% (0.2)

$N = \frac{2(1.96)^2 \times 0.24 \times 0.76}{0.2^2} = 35$

With the assumption that 90% (0.9) of patients that start this study will complete it, then actual sample size - $N = \frac{N}{0.9} = 39$ patients in each group.

A final minimum sample size of 39 in each group was computed after considering an attrition rate of 10%.

Using a computer generated table of numbers (Stat Trak), eligible patients were randomly allocated into 2 groups as they came to the clinic, based on the number chosen by the patient. These

numbers had been pre-assigned to a group. Group 1 was the 16G group, and Group 2 was the 18G group. A data form requesting for biodata, presenting symptoms, prostate findings on DRE, prostate volume on ultrasound scan, serum PSA result, post biopsy complications and the histopathology results (largest core size, smallest core size, cancer detection) was generated and completed by the researcher.

Study procedure

All patients had digitally guided trans-rectal biopsy of the prostate done on out-patient basis in the procedure room of the ward by the researcher. Patients were required to take light diet the day before the procedure, and empty their bowel on the morning of the procedure.

The patient was placed in the left lateral position, with the hips and knees flexed, neck flexed with the head facing the knees, with hands crossed over the chest. The perineum was cleaned with 10% cetrimide antiseptic solution and draped. A digital rectal examination was performed to assess the gland and then, 10mls of 2% xylocaine gel was instilled into the rectum as anaesthesia. Five minutes after application of the anaesthetic gel, under the guidance of the index finger of the right hand, the biopsy needle- size 16G group 1 and 18G group 2 was then be used to obtain 12 cores of prostate tissue from each lateral lobe of the gland. The tissues obtained were immediately preserved in 10% neutral buffered formalin, in a universal bottle, and taken to the laboratory for histopathological analysis by a single pathologist. Patients were observed for about one hour after the procedure on the ward, and then discharged with instructions to report back to the hospital in the event of any complications like: significant haematuria, severe rectal bleeding, acute urinary retention and fever with chills. The Visual Analog Scale VAS was administered to assess pain during and 15 minutes after the procedure, during the observation period. They were provided with an easy to use digitally clinical thermometer (intertronics, Kidlington. UK[®]) for twice daily recording of body temperature (at the axilla) for the first 5 days after the procedure, in the morning (about 8am) and in the evening (around 5pm). Since some degree of haematuria was expected after the procedure, the volume and characteristics of significant haematuria was explained to the patients. Acute retention of urine post biopsy was also assessed. All patients were given a handbill which explained the common complications from the procedure.

They reported at the follow up clinic at post-operative day 7 for review of complications, and on post-operative day 21 for review of histopathology result.

Outcome measures:

1. Cancer detection rate was measured as the proportion of participants in each group that had histologic diagnosis of adenocarcinoma of the prostate.
2. Quality of tissue obtained was assessed by degree of core fragmentation. Specimen found to have more than 12 cores at the time of histopathology analysis were taken as fragmented, and thus of poor quality (Inal et al., 2008). Samples reported as insufficient were also taken to be of poor quality (Inal et al., 2008).
3. Significant haematuria was taken as haematuria lasting more than 3 days, or requiring admission or blood transfusion.
4. Significant post-biopsy fever in this study was regarded as temperature greater than 38°C. Significant haematuria was regarded in this study as haematuria requiring intervention or lasting more than 3 days post biopsy.
5. Significant rectal bleeding described as the passage of bright red blood per rectum that requires intervention or lasts more than 3 days post biopsy.

Statistical analysis

Data was analyzed using Statistical Package for Social Sciences (SPSS) version 20.0 software.

Categorical data such as age group, level of education and presenting symptoms were presented as frequencies and proportions while continuous data such as largest core size, VAS and post biopsy temperature that were normal in distribution were presented as mean and standard deviation. PSA value, prostate volume and smallest core size that were not normally distributed were represented using median and interquartile range (IQR).

Chi-squared test of association was used to test for statistical association between categorical data such as core fragmentation, post biopsy complications and histologic findings and needle gauge 18G and 16G. The Fisher’s exact test was used in instances where the total expected cell counts less than five is more than 20% of the cells. Statistical inference was carried out using the independent sample t-test to compare means of numerical data such as means of largest core size, VAS and temperature post biopsy. The median test was for data such as smallest core size, PSA and prostate volume, cases where data was not normally distributed. The level of significance was set at $p < 0.05$.

The results are presented using statements, frequency distribution tables and charts in relation to the specific objectives of the study.

RESULTS

A total of 90 patients met the inclusion criteria and participated in this study, with 45 patients in group 1(16G), and 45 patients in group 2(18G)

Table 1: Socio-demographic characteristics of the participants

Variable	16G n=45	18G n=45
Age group	Proportion (%)	Proportion (%)
< 50 Years	2.2	4.4
51 – 60 Years	15.6	6.7
61 – 70 Years	46.7	44.4
>70 Years	35.6	44.4
Mean ± sd	68.4 ± 8.8	69.8 ± 8.5
Level of education		
No formal	37.8	35.6
Primary	20.0	17.8
Secondary	33.3	33.3
Tertiary	8.9	13.3

The mean (SD) age of the entire study population was 69.1 (8.6) years; mean (SD) age of 18G group was 69.8 (8.5) years while the mean (SD) age of the 16G group was 68.4 (8.8) years. Most of the participants in the study were in the 61-70 age group. Most of the participants in the study had no formal education (Table 1).

Nineteen (42.2%) of participants in the 16G group, and 17(37.8%) of those in the 18G group presented with a history of acute retention. There was a history of bone pain in 20 (44.4%) persons in 16G group and 21 (46.7%) persons in the 18G group; paraparesis was present in 16 (36.5%) persons in the 16G group and 13 (28.9%) in the 18G group.

Haematuria was reported by 12 people in the study. Only one patient had to be admitted for bladder irrigation and blood transfusion on account of significant haematuria (Table 2). The median (IQR) PSA value for 16G group was 32.1 (18.8-73.2) ng/ml while for the 18G was 28.4 (18.2-61.2) ng/ml. The median (IQR) serum PSA for the entire study population was 31.8 (17.9-69.3) ng/ml.

The median (IQR) prostate volume for the entire study population was 71.0 (47.4-100.3) mls (Table 3). An equal number of persons in both groups had haematuria. There was no statistically significant difference in haematuria among the 18G or 16G groups (p=1.000) There was no statistically significant difference in rectal bleeding among the 16G or 18G groups (p=1.000).

Table 2: Presenting symptoms of study population

Variable	16G n=45		18G n=45	
	Frequency	Percent	Frequency	Percent
Acute Retention				
Yes	19	42.2	17	37.8
No	26	57.8	28	62.2
Bone Pains				
Yes	20	44.4	21	46.7
No	25	55.6	24	53.3
Paraparesis				
Yes	16	35.6	13	28.9
No	29	64.4	32	71.1
Weight Loss				
Yes	16	35.6	14	31.1
No	39	64.4	31	68.9
Haematuria				
Yes	8	17.8	4	8.9
No	37	82.2	41	91.1
Chest Pain				
Yes	2	4.4	3	6.7
No	43	95.6	42	93.3

Table 3: PSA value and prostate volume of study group

Variable	16G (n=45) Median (IQR)	18G (n=45) Median (IQR)
Serum PSA	32.1 (18.8-73.2)	28.4 (18.2-61.2)
Prostate volume	77.8 (54.7-113.6)	58.3 (45.0-92.9)

Table 4: Post biopsy complication of study population

	16G n (%)	18G n (%)	Fisher's Exact value	p-value
Haematuria				
Yes	4 (8.9)	4 (8.9)	0.001	1.000
No	41 (91.1)	41 (91.1)		
Rectal Bleeding				
Yes	3 (6.7)	3 (6.7)	0.001	1.000
No	42 (93.3)	42 (93.3)		
Immediate Chills & Rigor				
Yes	1 (2.2)	4 (8.9)	1.906	0.361
No	44 (97.8)	41 (91.1)		
Acute Retention				
Yes	0 (0.0)	1 (2.2)	1.011	1.000
No	45 (100)	44 (97.8)		
Epididymo-Orchitis				
Yes	2 (4.4)	4 (8.9)	0.714	0.677
No	43 (95.6)	41 (91.1)		

One person in the 16G group compared to 4 persons in the 18G group had chills and rigors as a post biopsy complication. There was no statistically significant difference in chills and rigors among the 16G or 18G groups ($p=0.361$).

One (2.2%) person in the 18G group compared to none in the 16G group had acute retention as a post biopsy complication. There was no statistically significant difference in acute retention among the 18G or 16G groups ($p=1.000$). There was no statistically significant difference in epididymo-orchitis among the 16G or 18G groups ($p=0.677$). (Table 4)

There was no statistically significant difference in the length of the largest core sizes in the 16G or 18G group ($p=0.660$). There was no statistically significant difference in the length of the smallest core sizes in the 18G or 16G group ($p=1.000$). Thirty four (73.9%) respondents in the 16G group had core

size of 12 compared to 12 (26.1%) respondents in the 18G group. There was a statistically significant difference in core sizes within the 16G and 18G groups ($p < 0.0001$) (Table 5).

The cancer detection rate in the 16G group was 48.9% ($n=22$) while 46.7% ($n=21$) of study participants in this 16G group had benign findings. In 4.4% ($n=2$) there was inadequate samples for a proper result (Table 6).

The cancer detection rate in the 18G group was 44.5% ($n=20$) while 53.3% ($n=24$) of study participants in this 18G group had benign findings. In 2.2% ($n=1$) there was inadequate samples for a proper result. The cancer detection rate in the entire study population was 46.7% ($n=22$).

There was no statistically significant difference in Gleason grading rates between 18G and 16G groups. ($p=0.095$) (Table 7).

Table 5: Number of core tissue obtained after biopsy among study groups

Core Number	16G n (%)	18G n (%)	p-value
12	34 (73.9)	12 (26.1)	<0.0001
>12	11 (25.0)	33 (53.7)	

Table 6: Outcome of biopsy among the study population

Variable	16G n= 45 Proportions (%)	18G n = 45 Proportions (%)
Benign	46.7	53.3
Malignant	48.9	44.5
Others	4.4	2.2

Table 7: Histologic findings among the study population

Variable	16G n (%)	18G n (%)	Fisher's exact test	p-value
Histology				
Adenocarcinoma	22(48.9)	20 (44.5)	0.718	0.750
Nodular Hyperplasia	21(46.7)	24 (53.3)		
Inadequate sample	0(0.0)	1 (2.2)		
Chronic prostatitis	1(2.2)	0(0.0)		
Prostatic intraepithelial neoplasia	1(2.2)	0(0.0)		
Gleason grade				
Low (2-6)	8 (38.1)	13 (61.9)	4.825	0.095
Intermediate (7)	10 (76.9)	3 (23.1)		
High (8-10)	4 (50.0)	4 (50.0)		

DISCUSSION

Prostate cancer remains one of the most commonly diagnosed cancer among Nigerian men, accounting for 11% of all male cancers (Ogunbiyi & Shittu, 1999) hence the need for more accurate means of diagnosis. An accurate means of diagnosis remains the use of histopathologic

analysis of tissues gotten from transrectal ultrasound guided biopsy of the gland. This study investigated the outcome of transrectal prostate biopsy with 16G trucut biopsy needle in comparison with 18G trucut biopsy needle and revealed that using 16G needle results in better

quality of tissues, without increasing patient discomfort or other complications.

The mean (SD) age of patients in this study was 69.1 (8.64) years, with age range of 47-85 years.

The peak age range in both groups was 61 to 70 years. The mean (SD) age of patients diagnosed with cancer was 68.3 (9.8) years. This may have been because the study was carried out in UBTH, which is a tertiary health institution and thus a referral center, so most of the patients seen are those with the suspicion of prostate cancer. This finding is similar to what was found in some other studies carried out in the Western part of Nigeria, by Osegbe et al. (1997), Ojewola et al. (2012) and Badmus et al. (2010), where the peak age of patients was 68, 67.2, and 68 years respectively.

Most patients in Nigeria tend to present to the hospital at a late stage of the disease, and this may account for the presentation of patients with features suggestive of advanced disease. There are also no population screening programs available in Nigeria for prostate cancer, hence most patients present to the hospital when they are symptomatic, or as incidental findings of elevated PSA when being evaluated for other diseases. This is similar to the finding by Ojewola et al. (2012) in their study, where most patients also presented with features of metastasis.

The main objectives of this study were to determine whether the 16G needles produced larger cores of tissue (quantity), with less fragmentation of the cores (quality). The mean (SD) largest core taken overall in this study was 1.93cm (0.62), with the mean largest core size using the 16G needle being slightly larger than that using the 18G needle, which can be explained by the fact that 16G needles are larger than 18G needles. This difference was however not statistically significant.

Significant core fragmentation was however seen with cores taken using the 18G needles (33 patients), unlike what was seen with cores taken using the 16G needle (11 patients). This difference in core fragmentation rate was statistically significant, showing that the 16G needles, which have a larger caliber, give better quality of tissues. The finding of better quality of tissues using 16G needles is similar to what was found by Saredi et al. (2009) and Inal et al. (2008) where 16G needles gave significantly less fragmentation of tissues, hence better quality of tissues. It can thus be inferred that improving the quality of tissues may in turn reduce the rate of reports of inadequate tissue for sampling and in turn, improve the rate of cancer detection, with less need for repeat biopsy.

The overall cancer detection rate in this study was 46.7%, with a total of 42 cases of adenocarcinoma of the prostate detected in both groups. This cancer detection rate is similar to what was seen by Ojewola et al. (2012) in a study carried out in Lagos, where the cancer detection rate was 48.8%.

The 16G needles detected slightly more cases of cancer 22 cases (48.9%), than the 18G group where 20 cases (44.5%) were detected, an improvement in cancer detection of 4.4%. This was however not statistically significant, and may be accounted for by the slightly larger prostate volume of the patients that had biopsy using 16G needles. Patients in the 16G group reported slightly higher pain scores, using VAS, both during the procedure, and 15 minutes after the procedure. Transrectal prostate biopsy using 16G needle results in better quality of tissues, without increasing patient discomfort or other complications.

In essence, increasing the size of the needle used from 18G to 16G does not increase the pain/discomfort the patients perceive during prostate biopsy, regardless of the type of anaesthesia used. There was no statistically significant difference in the complication rates of both groups, showing that in addition to not increasing patient discomfort during the procedure, 16G needles also did not increase the post biopsy complications.

This is similar to the findings of previous studies carried out by Saredi et al. (2009), Inal et al. (2008) McCormack et al/ (2012) and Cicione et al. (2012) Most of the complications in this study were self-limiting, probably as a result of the antibiotic regimen used, the patient preparation, the biopsy technique, and the strict adherence to the exclusion criteria. Only one patient had to be admitted for bladder irrigation and blood transfusion on account of significant haematuria.

This study has therefore noted an improvement in quality of tissues obtained using the 16G needles, but it is uncertain if this will translate to an improvement in cancer detection rates in a larger study, or if individual cores were analyzed, as regards measurement of cancer per core, number of positive cores, percentage of cancer per core, and percentage of cancer in the entire specimen, as is presently advocated by urology pathologists (Vanverder Kwast et al., 2003).

Limitation of the study

The biopsies were digitally guided, without the aid of transrectal ultrasound guidance, which is the standard. Thus, systematic sampling of the prostate gland could not be done. Transrectal ultrasound was not available in our institution, at the time the study was carried out.

The small sample size, was just a little above the minimum sample size for this study, and thus may not be an accurate representation of the larger population. This sample size had to be used due to the time constraint of the study. The temperature readings were taken by the individual patients, and thus subject to error. The lack of blood culture pre and immediately post biopsy negated proper identification of those with bacteraemia before the procedure.

CONCLUSION

In this prospective randomized comparative study, the use of 16G needles improved the quality of tissues obtained from digitally guided prostate biopsy but did not improve the quantity of samples obtained. The use of 16G needles for trans rectal digitally guided prostate biopsy, did not improve the cancer detection rate, when compared to 18G needles. There was no increase in patient discomfort, and other post biopsy complications when the larger 16G needles were used, as compared to the 18G needles.

RECOMMENDATION

The use of size 16G needles for digitally guided biopsy of the prostate is recommended, as they increase the quality of tissues obtained, thereby potentially reducing the rate of repeat biopsy.

The 16G needle for prostate biopsy could be adopted for routine use, since no statistically significant difference in morbidity was noticed between 16G and 18G needles.

However, the use of trans rectal ultrasound guided biopsy, rather than digitally guided biopsy is recommended.

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Conflict of interest

There is no conflict of interest to declare.

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