Study Protocol

A Study Protocol for Assessing the Correlation of USG Guided Fine Needle Aspiration Cytology and Histopathology of Intra-abdominal Masses

ABSTRACT

Background: Deeply situated, solitary or nonpalpable lesions of abdomen are a common problem in surgical practice and are generally hard to evaluate. impair the quality of life and may have poor prognosis leading to higher mortalities. By using imaging technique difference between malignant and non-malignant lesions is generally done. USG guided FNAC of intra-abdominal masses is a good diagnostic modality to facilitate treatment planning. Histopathological correlation aids in sensitivity and specificity of Ultra sound guided FNAC thereby making it first investigation of choice for evaluation of intra-abdominal masses. This study attempts to assess the utility of Ultra sound guided fine needle aspiration cytology of intra-abdominal masses and their histopathological correlation.

Methodology: This Prospective study will be conducted in Cyto-histopathology division of Department of Pathology, JNMC, Wardha. Total 30 patients with abdominal masses will be enrolled in the study. Fine needle aspiration of the abdominal lump will be done in the Department of Radiology, using real time USG. The data will be analysed using appropriate statistical programmes.

Expected Results: A significant correlation is expected between histopathology and ultrasound guided fine needle aspiration cytology of intra-abdominal masses.

Conclusion: Conclusion will be drawn from on the basis of results obtained from this study.

Key words: Ultrasound, Intra-abdominal masses, Fine needle aspiration cytology, Correlation.

INTRODUCTION

Deeply situated, solitary or nonpalpable lesions of abdomen are frequently hard to evaluate. For better patient management it is vital to differentiate between non neoplastic and neoplastic lesions and importantly lesions with inflammatory aetiology. By using imaging technique difference between malignant and non-malignant lesions is generally done. With the increasing use of radiological techniques identification of relatively small lesions can be

achieved with consistent targeting, but the diagnosis is mainly reliant on obtaining precise tissue specimen collection, which is often done by transcutaneous tissue aspiration. [1]

Cytopathology is a major diagnostic technique and there has been an increase in the number of FNACs performed during the last 15 years, since it was first instituted by Martin and Ellis in 1930. [2]. FNAC under image guidance has brought about revolution in the field of cytological diagnosis. Because of high degree of accuracy and minimum discomfort to the patient through this technique permits the accurate localisation of non- palpable and deep-seated lesion in the body. Image guided FNAC is routinely done in when single and multiple lesions are located in inaccessible site. It is very important to confirm the diagnosis as well essential for both initiation of treatment and categorisation of cancer according to stage. [3]

USG proposes numerous benefits as a guidance system for biopsy. It is quite affordable, easily available and mobile; it can provide imaging in many tissue planes like transverse, longitudinal and oblique. It is free of harmful ionizing radiation. The utmost benefit of this system is that needle tip can be seen while performing USG (real time) and this tip can be seen passing through various tissue levels of the target area. [4] In case of malignant lesions FNAC has shown 100% specificity and is considered to be the first choice for evaluation of abdominal lesions.[5,6,7]. These advantages emphasize the need to establish USG guided FNAC of intra-abdominal masses as a diagnostic modality and facilitates treatment planning. Histopathological correlation aids in sensitivity and specificity of Ultra sound guided FNAC thereby making it first investigation of choice for evaluation of intra-abdominal masses.

RESEARCH GAP: The aim of present study to assess the utility of "Ultra sound guided fine needle aspiration cytology of intra-abdominal masses and their histopathological correlation."

RESEARCH QUESTION:

With the understanding of results obtained from "USG guided fine needle aspiration cytology of intra-abdominal masses and their associated histopathological evaluation", the following research question is framed-

"Does correlation exists between histopathology and ultrasound guided fine needle aspiration cytology of intra-abdominal masses."

METHODOLOGY:

STUDY DESIGN - Observational, analytical and prospective.

PLACE OF STUDY – Department of Pathology, JNMC, Sawangi (Meghe), Wardha, Maharashtra.

DURATION – 2020 to 2022 (2 years)

METHODS –
Prior informed consent will be taken from the patients participating in the study. Total 30 cases with clinical or radiological diagnosis of intra-abdominal mass will be studied . Thorough clinical data in terms of patient's history, physical examination findings will be taken and related investigations will be done. The patients will undergo radiological examination (ultrasonography) to determine the source of the mass and its association with

the nearby organs. Fine needle aspiration of the abdominal lump will be done in the Department of Radiology, using real time USG in aseptic environment, using shortest route to target area, as to be recommended by the radiologist. The coagulation profile of all patients with abdominal mass will be done. A commercial disposable 22-gauge needle fitted to a 10ml plastic syringe will be utilized. For deeply situated lesions, 9cm long 22 -gauge spinal needle will be utilized. Several smears will be made and promptly will be fixed with 95% alcohol fixative. These smears will be stained by using 'Papanicolaou's stain and Haematoxylin and Eosin stain (H & E).' Smears will be air dried and stained with Giemsa stain. Whenever required special stains such as 'Ziehl Neelsen' and 'Periodic Acid Schiff' can be utilized. Whenever fluid will be obtained, macroscopical evaluation of fluid and centrifugation will be done. Smears will be made from sediment and then stained by appropriate stains. Each smear will be examined after staining under 10X magnification to get idea of overall cellularity, then under 40X magnification to get morphological details of individual cells. The smear will be categorized into inflammatory, benign, malignant lesions on the basis of individual cell and nuclear morphology. Resected intra-abdominal masses will undergo histopathological evaluation and correlation will be made with outcome of USG directed fine needle aspiration cytology. The collected data will be tabulated and results will be calculated and analysed by using appropriate statistical methods.

SAMPLE SIZE – 30 patients

n = $\frac{4pq}{L^2}$

Where,

p = Proportion of diagnostic yield = 93.9%

q = 100- p =100- 93.9 = 6.1

L = Allowable error

= 10% of p

= 10 x 93.9/100

= 9.39

n = $\frac{4\times93.9\times6.1}{9.39^2}$

= 25.96

n = 30 patients needed in the study

Study reference: Jinu Abraham Glason et all

Formula reference: VK Chadha, "Sample size determination in health studies, NTI Bulletin, 2006, 42/3 and 4, 55-62."

Inclusion criteria:

1. Subjects with clinically or radiologically diagnosed abdominal masses referred to Department of Pathology.
2. Patients with normal coagulation profile

Exclusion criteria:

1. Subjects with abnormal coagulation profile or bleeding disorders
2. Patients in which peritonitis is suspected
3. Pregnant women
4. Non-cooperative patients.
5. Patients in which extra-hepatic jaundice(obstructive), haemangioma (hepatic surface)

   And cysticercosis are suspected.
6. Swellings arising from uterus, cervix, prostate, bone and abdominal wall.

Statistical Analysis

Proportions, Chi square/t-test for proportions, bars, charts, contingency tables, frequencies and percentages will be used for statistical evaluation.

EXPECTED RESULTS:

The study will be conducted for a period of 2 years and all the observations will be depicted in a well-tabulated master chart.

DISCUSSION:

Khan AA et al did a study on cytological diagnosis obtained by FNA of abdominal masses. They confirmed cytological findings with histopathology. Total of 50 patients were studied and no false positive results were found.[8]

A comparative study of classical FNA and image guided FNA of intra-abdominal lumps by **Nautiyal S et al** showed improved diagnostic accuracy with guided aspirations.[9]

Sobha Rani et al studied 100 cases with deep seated lesions subjected to ultrasound guided FNAC and found that most of patients in the study were found to be in their 5th decade and male to female ratio was 3:1. Most of the lesions were recognised as malignant where liver was found to be most commonly involved organ. They reported a specificity of 100% and sensitivity of 90%.[10]

Hemalatha et al included 100 patients who were having either clinically or radiologically diagnosed abdominopelvic masses in their study. USG directed FNAC was performed. Diagnostic accuracy rates of benign, malignant and non-neoplastic lesions were 100%, 96% and 94.4% respectively. The over-all accuracy rate was found to be 96.3%. They concluded that "USG guided FNA is a quick, affordable, highly precise and a harmless diagnostic procedure which can prevent a long-lasting and expensive workup in different types of abdominopelvic masses."[4]

Bhargava R et al conducted a study which was prospective in nature, to access the role of FNAC in intra-abdominal masses. They studied 104 patients having intra-abdominal masses. Cyto-histopathological correlation was made in 34 patients. They reported sensitivity, specificity and efficacy of 100% each for neoplastic lesions.[11]

Islam T et al studied 78 patients with intra-abdominal masses and performed ultrasound guided fine needle aspiration cytology. Objective of their study was to access utility of image guided FNA as an important diagnostic tool for evaluation of intra-abdominal lesions. Out of total 78 patient's majority i.e. 59 patients (75.6%) were males and 19 (24.4%) were females. 29(37.2%) were found to be benign, while 41(52.6%) were malignant and remaining 8(10.3%) were found to be nonrepresentative (contained only blood). Liver abscess was found to be most common benign lesion accounting 19(24.4%) of all lesions. 26(33.3%) cases were of primary malignancy while that of secondary were 15(19.2%). The sensitivity of their study was 89.7%. They concluded that "ultrasound guided FNAC is a sensitive investigative method in a wide range of intra-abdominal neoplastic and non-neoplastic lesions." [1]

Mishra BM et al evaluated intra-abdominal lumps where special reference was given to ultrasonography and FNAC. Eighty cases were included in the study. Male predominance was observed and malignancies were more common than benign lesions. Amongst the malignancies, carcinoma of stomach (45%) was the most common. False positive and negative diagnosis in the study was noted to be 2.5% and 15% respectively. The diagnostic accuracy was recorded to be 82.5%.[12]

Pereiras RV et al used Chiba needle. Their technique permitted that without doing high risk exploratory surgery cytological diagnosis of malignancy can be done. Which also suggested that this technique can prevent prolonged hospitalization of patient and also early initiation of treatment is quite possible.[13]

Ahmed SS et al did a study on 200 patients with abdominal lump. These patients were subjected to USG guided FNAC and cytohistological correlation was done. Overall sensitivity and specificity were 94.11%, 100%, respectively, with 95.7% of diagnostic accuracy [14]

Abdominal masses are known to propose clinical dilemma to the surgeon. So, differentiation between neoplastic and non-neoplastic lesions are crucial, especially in case of advanced non resectable neoplastic lesions to prevent exploratory laparotomy. FNA is considered to be more precise and sensitive than core needle biopsy.[15]

Ultrasonography (USG), a new diagnostic imaging technique, that has enhanced the outcome of surgical biopsies in terms of localization of lesions which are difficult to access as well diagnostic accuracy. For deeply situated lesions image guided FNA found to be a good modality with high sensitivity. It has reduced time taken to diagnose a lesion as it can

be performed as the first step in the patient's diagnostic workup, thereby it can be considered as satisfactory rapid diagnostic tool for the clinician.[4]

In this modern era of technology different types of tissue imaging techniques like fluoroscopy, computerized tomography (CT), ultrasound (USG) are available which we can use as a guide for FNA of abdominal masses. But, out of all these, ultrasonography has an upper hand over others because of its rapidity, reproducibility and versatility. It is safer as no ionizing radiation are used.[9] As we know Maximum of the intra abdominal masses are clinically non-palpable and even if they are palpable, it is very difficult to know the extent, shape and size of lesion.[14] Before initiation of therapy, a documented evidence of the type of the pathology is obligatory. It is also important for prognostication of disease. In most of the cases, results achieved by FNAC can be utilized as substitute for surgical procedures like diagnostic laparotomy.[16]

FNA is an ideal outpatient procedure which can be used for the diagnosis of lesions of any location. Accuracy and benefits of FNAC are backed by many literatures but they also stated need for caution in interpretation. This technique also requires meticulous attention as it has its own limitations in terms of diagnosis.[17]

The benefits which makes USG superior than CT scan for FNA are that it is quick, cheap, and versatile, also without any risk of radiation exposure, can be easily repeated when necessary & no contrast medium is required.[18]

Many authors have narrated about benefits of directed transcutaneous FNA of suspected abdominal mass lesions and retroperitoneal lesion. Contribution of this technique in formulation of further patient management was stressed.[19,20,21]. Similar studies were reported by Rashmi S. et. al. [22], Yeola et. al. [23,24]. Few of the related studies were reviewed [25-35].

REFERENCES:

1. Islam T, Hossain F, Rumpa AP, Sikder NH, Bhuiyan MA, Karim E, et al. Ultrasound guided fine needle aspiration cytology: a sensitive diagnostic tool for diagnosis of intra-abdominal lesions. Bangladesh Med Res Counc Bull 2013; 39:14-7.
2. Martin HE, Ellis EB: Biopsy by needle puncture and aspiration. Ann Surg 1930; 92:169-81.
3. Boiselle PM, Patz EF, Vinning DJ, Weissleder R, Shepard JA, McLound TC. Imaging of mediastinal lymph nodes: CT, MR and FDGPET. Radiographics 1998; 18:1061-1069.
4. Hemalatha AL, Sumana V, Sushma S, Suma JK, Varna I, Anubha Aditya. Ultrasound Guided FNAC of Abdominal-Pelvic masses: The Pathologist's Perspective Journal of Clinical and Diagnostic Research 2013 Feb;7(2):273-7.
5. Pitman MB. Fine needle aspiration biopsy of the liver. Principle diagnostic challenges. Clin Lab Med 1998;18:483-506.
6. Joao Nobrega and Guimaraes dos Santos. Aspirative cytology with fine-needle in the abdomen, retroperitoneum and pelvic cavity: a seven year experience of the Portuguese Institute of Oncology, Centre of Porto. European Journal of Surgical Oncology. 1994; 20:37-42.
7. Joseph T., Ferrucci Jr. MD., Jack Wittenberg MD. CT Biopsy of Abdominal Tumors: Aids for Lesion Localization. Radiology 1978; 129: 739-744.

8. Khan AA, Jan GM, Wani NA. Fine needle aspiration of intra-abdominal masses for cytodiagnosis. J Indian Med Assoc 1996;94(5):167-8.
9. Nautiyal S, Mishra RK, Sharma SP. Routine and ultrasound guided FNAC of intra-abdominal lumps – A comparative study. J Cytol 2004;21(3):129-32.
10. Sobha Rani G, Md K Faheem N, Sai Prasad B V, Sudhakar Reddy E. Efficiency of ultrasound guided aspiration cytology in deep seated lesions - a diagnostic evaluation. Int J Med Health Sci 2012;1(1):1-12.
11. Bhargava R, Sharma T, Hiremath SS, Kumar P, Verma N, Sharma J. A study of intra-abdominal masses in and around Davangere. Journal of Advance Researches in Biological Sciences 2013;5(3):290-3.
12. Mishra BM, Mohapatra CKR, Bishi PR. Evaluation of abdominal mass with special reference to FNAC and Ultrasonography: a prospective study. Asian J Pharm Hea Sci 2014;4(3):1083-7.
13. Bottlesk, Miller TR, Cohen MB, Ljung BM. Fine needle aspiration biopsy: has its time come ? Am J Med 1986;81:525-31.
14. Ahmed SS, Akhtar K, Akhtar SS. Ultrasound guided fine needle aspiration biopsy of abdominal masses. JK Science. 2006;8:200-4.
15. Stewart CJR, Coldewey J, Stewart IS. Comparison of fine needle aspiration cytology and needle core biopsy in the diagnosis of radiologically detected abdominal lesions. J Clin Pathol. 2002;55:93–97.
16. Sidhaling Reddy, Sainath K. Fine Needle Aspiration Cytology of Intra-Abdominal Lesions. Journal of Clinical and Diagnostic Research 2011 Jun;5(3):551-8.
17. Frable WJ. Fine needle aspiration biopsy. Human Pathology 1983 Jan;14(1):9-28.
18. Jha BM, Shah R, Patel J. Effectiveness of image guided fine needle aspiration cytology in cases of deep seated lesions. Int J Med Sci Public Health 2013; 2:439-42.
19. Khan AA, Jan GM, Wani NA. Fine needle aspiration of intra-abdominal masses for cytodiagnosis. J Indian Med Assoc 1996;94(5):167-8.
20. Bret PM, Fond A, Carola G, Bretagnolle M, Lacour MJG, Bret P, et al. Abdominal lesions: A prospective study of clinical efficacy of percutaneous fine needle biopsy. Radiol 1986;159:345-6.
21. Ferrucci JT, Wittenberg J. CT Biopsy of abdominal tumors: Aids for lesion localization. Radiol 1978;129:734-44.
22. Rashmi, S., S.N. Jajoo, and A. Belsare. “Assessment of Correlation between Clinical Examination and Investigations with Outcome in Cases of Abdominal Malignancy.” International Journal of Pharmaceutical Research 11, no. 3 (2019): 1465–68. https://doi.org/10.31838/ijpr/2019.11.03.163.
23. Yeola, M.E., D. Gode, and A.K. Bora. “Diagnostic Laparoscopy as an Effective Tool in Evaluation of Intra-Abdominal Malignancies.” World Journal of Laparoscopic Surgery 11, no. 2 (2018): 68–75. https://doi.org/10.5005/jp-journals-10033-1338.
24. Yeola, M.E., D. Gode, and A.K. Bora. “Evaluation of Abdominal Malignancies by Minimal Access Surgery: Our Experience in a Rural Setup in Central India.” World Journal of Laparoscopic Surgery 11, no. 3 (2018): 115–20. https://doi.org/10.5005/jp-journals-10033-1350.
25. Pattabiraman, S., S.V. Phatak, P.A. Patwa, and G. Marfani. “Bilateral Sporadic Renal Angiomyolipoma .Ultrasonography and Computed Tomography Imaging.” Journal of

Datta Meghe Institute of Medical Sciences University 15, no. 1 (2020): 134–35. https://doi.org/10.4103/jdmimsu.jdmimsu_199_19.
26. Patwa, P., S. Phatak, S. Pattabiraman, and G. Marfani. “Ultrasound and Color Doppler Features of Transitional Cell Carcinoma of the Endometrium with Pathological Correlation.” Journal of Datta Meghe Institute of Medical Sciences University 14, no. 4 (2019): 429–31. https://doi.org/10.4103/jdmimsu.jdmimsu_198_19.
27. Sadavarte, T.P., N.O. Bansal, P. Banode, and M. Padmawar. “Role of High Resolution ultrasonography and Color Doppler in Evaluating and Distinguishing the Type of Inguinal hernia.” International Journal of Current Research and Review 12, no. 14 Special Issue (2020): 135–40. https://doi.org/10.31782/IJCRR.2020.135140.
28. Rai A, Datarkar A, Borle RM. Are maxillomandibular fixation screws a better option than Erich arch bars in achieving maxillomandibular fixation? A randomized clinical study. Journal of oral and maxillofacial surgery. 2011 Dec 1;69(12):3015-8.
29. Agrawal A, Timothy J, Cincu R, Agarwal T, Waghmare LB. Bradycardia in neurosurgery. Clinical neurology and neurosurgery. 2008 Apr 1;110(4):321-7.
30. Bourne R, Steinmetz JD, Flaxman S, Briant PS, Taylor HR, Resnikoff S, Casson RJ, Abdoli A, Abu-Gharbieh E, Afshin A, Ahmadieh H. Trends in prevalence of blindness and distance and near vision impairment over 30 years: an analysis for the Global Burden of Disease Study. The Lancet Global Health. 2021 Feb 1;9(2):e130-43.
31. Borle RM, Nimonkar PV, Rajan R. Extended nasolabial flaps in the management of oral submucous fibrosis. British Journal of Oral and Maxillofacial Surgery. 2009 Jul 1;47(5):382-5.
32. Agrawal A, Cincu R, Goel A. Current concepts and controversies in the management of non-functioning giant pituitary macroadenomas. Clinical neurology and neurosurgery. 2007 Oct 1;109(8):645-50.
33. Franklin RC, Peden AE, Hamilton EB, Bisignano C, Castle CD, Dingels ZV, Hay SI, Liu Z, Mokdad AH, Roberts NL, Sylte DO. The burden of unintentional drowning: global, regional and national estimates of mortality from the Global Burden of Disease 2017 Study. Injury prevention. 2020 Oct 1;26(Supp 1):i83-95.
34. Chole RH, Gondivkar SM, Gadbail AR, Balsaraf S, Chaudhary S, Dhore SV, Ghonmode S, Balwani S, Mankar M, Tiwari M, Parikh RV. Review of drug treatment of oral submucous fibrosis. Oral oncology. 2012 May 1;48(5):393-8.
35. Korde SD, Basak A, Chaudhary M, Goyal M, Vagga A. Enhanced nitrosative and oxidative stress with decreased total antioxidant capacity in patients with oral precancer and oral squamous cell carcinoma. Oncology. 2011;80(5-6):382-9.