IJSRM
INTERNATIONAL JOURNAL OF SCIENCE AND RESEARCH METHODOLOGY
An Official Publication of Human Journals

Human Journals
**Review Article**
December 2018 Vol.:11, Issue:2


# Understanding the Systematic Review Literature on Ultrasound Assists with Moving Forward with Haptic Robotic Technology

IJSRM
INTERNATIONAL JOURNAL OF SCIENCE AND RESEARCH METHODOLOGY
An Official Publication of Human Journals

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**Submission:** 24 November 2018
**Accepted:** 30 November 2018
**Published:** 30 December 2018

HUMAN JOURNALS
**www.ijsrm.humanjournals.com**

**Keywords:** Ultrasonography, Robotics, Diagnosis, Mass Screening.

**ABSTRACT**

**Introduction:** Telehealth [transmitting voice, data, images and information remotely *via* telecommunications technologies reduces travel time. Objective: Priester and colleague's manuscript reviewed the robotic ultrasound systems over two decades. An early prototype of a revolutionary haptic (force feedback) robot for diagnostic ultrasound was announced by Deakin University in partnership with Telstra. A haptic robot connected to rural ultrasound equipment allows remote robotic 'arm' control with movements sent in real time across the 4G network. Implementation for routine diagnosis or mass screening of susceptible individuals exists, with potential cost savings but trials must focus on remote diagnosis of medical conditions that result in positive health outcomes or cost benefits, hence the abstract author independently reviewed the ultrasound systematic review literature. Methods: Twenty-one systematic reviews on ultrasound screening or diagnosis were identified including reviews for diagnosis of breast cancer detection, acute maxillary sinusitis, suspected subacromial disorders, juvenile idiopathic arthritis, thyroid lesions / nodules, DVT, cholelithiasis, retinal detachment, carotid artery stenosis, common bile duct stones, appendicitis/ gallstones, pneumonia, pancreatic mass lesions, fetal assessment and screening to detect abdominal aortic aneurysm. Various diagnostic details documented included; sensitivity, specificity, false positive/negative rates, cost and mortality benefit, value, performance, other recommendations or insufficient evidence. Results: Ultrasound is recommended for diagnosing various medical diseases and conditions. Indications are that abdominal aortic aneurysm diagnostic screening in risk groups maybe considered in terms of conducting pilot trials for testing capability and functionality. Conclusions: These results are interesting to review prior to development of pilot studies of remote robotic technology.

## INTRODUCTION

Telehealth; transmitting voice, data, images and information remotely via telecommunications technologies can reduce the need for patients or health professionals to travel. Priester and colleague's manuscript reviewed the robotic ultrasound (US) systems developed over two decades [Priester et al 2013]. In addition, an early prototype of a revolutionary haptic (force feedback) robot for diagnostic US was announced by Deakin University in partnership with Telstra. A haptic robot connected to rural US equipment allows the sonographer or Doctor to remotely control the robotic 'arm' with movements sent in real time across the 4G network. Possibilities for replication and implementation for routine diagnosis or mass screening of susceptible individuals exists, with potential cost savings however, it is important that robotic US trials focus on remote diagnosis of medical conditions that will result in positive health outcomes or cost benefits, hence the abstract author independently reviewed the US systematic review literature.

### Literature searching methodology

The Cochrane Library [http://onlinelibrary.wiley.com/cochranelibrary/search/] was searched using search terms; "ultrasound diagnosis". 47 records were retrieved, 7 protocols were not reviewed, 19 diagnostic (Dx) reviews were reviewed. Interestingly, a few not labelled as Dx were also reviewed as in fact they were diagnostic with one example being; screening programs for developmental dysplasia of the hip in newborn infants. The search string/terms' ultrasonography AND systematic review AND diagnosis' was also used to locate records from other reviews and trials listed in the Cochrane Library. 46 records were retrieved from other reviews. US that was one of the following; Endoscopic Ultrasound (EUS), EUS fine-needle aspiration, endobronchial ultrasound (EBUS) guided transbronchial needle aspiration, EUS- fine needle aspiration, EBUS transbronchial needle biopsy or rectal ultrasound were not reviewed. This was for the reason that the literature review is focused on reviewing basic US that could be developed in light of the revolutionary haptic (force feedback) robot for diagnostic US mentioned above. More complicated US or variations of US techniques were not applicable to review.

## RESULTS

Twenty-one systematic reviews/meta-analysis were retrieved that are listed below that report that US was useful, recommended, accurate and/or preferred over other diagnostic tests.

Breast cancer detection [Nothacker M et al. 2009]

– 6 cohort studies, level of evidence (3b). Supplemental breast US in women with mammographically dense breast tissue (ACR 3 & 4) permits detection of small, otherwise occult breast cancers. Potential adverse impacts for women in this intermediate risk group are associated with an increased biopsy rate.

Acute maxillary sinusitis [Varonen H et al. 2000]

– 49 study reports were found, 11 articles on studies n = 1144. Using radiography or US improves the accuracy of diagnosis. Clinical examination is a rather unreliable method for diagnosing this condition even in the hands of experienced specialists.

Suspected subacromial disorders [Ottenheijm RP et al. 2010]

– 23 studies. US is strongly recommended in patients for whom conservative treatment fails. This is to rule in or out full thickness tears or to rule in partial thickness tears and to a lesser extent to diagnose tendinopathy, subacromial bursitis and calcifying tendonitis.

Juvenile idiopathic arthritis [Collado P et al. 2012]

– 20 studies, knee most commonly studied. US is a valuable tool for detecting synovitis in juvenile arthritis. It demonstrated higher sensitivity (sens) in assessing synovitis as compared to clinical examination.

Thyroid lesions [Yu D et al 2014]

– 7 studies 597 thyroid nodules. Contrast enhanced US is a promising non-invasive technique for the differential diagnosis of benign and malignant thyroid nodules. It could be a valuable supplemental method to fine-needle aspiration.

Thyroid nodules [Razavi SA et al. 2013]

– 24 studies n = 2624. Evaluation of thyroid nodules with US elastography appears to be both more sensitive and specific then each of the US features. The former is a safe and effective technique that warrants further rigorous investigation or use in the clinical diagnosis of thyroid nodules.

Appendicitis and gallstones [Carroll PJ et al. 2013]

– 8 studies n= 1268. Pooled sens 92%, pooled spec 96%. Surgeon performed US achieves acceptable sens and spec for diagnosis of both gallstones and appendicitis. Data regarding cost-effectiveness are lacking.

Asymptomatic patients after orthopaedic surgery to diagnose Deep Venous Thrombosis (DVT) [Wells PS et al 1995]

– 17 studies. Level 1 studies US sens 62%, spec 97%, level 2 studies sens 95%, spec 100%. Venous US imaging has only moderate sens and a moderate positive predictive value when used to screen for DVT in patients after orthopaedic surgery.

DVT [Kassai B et al. 2004]

– 31 studies. Our results suggest that particularly for proximal veins US is accurate for the diagnosis of DVT in asymptomatic post op orthopaedic patients.

DVT [Goodacre S et al. 2005]

–100 cohorts comparing US to venography in patients with suspected DVT. Overall sens for proximal DVT was 94%, for distal DVT was 64% and spec was 94%. Combined colour doppler US techniques have optimal sens while compression US has optimal spec for DVT. US has largely replaced contrast venography.

DVT [Pomero F et al. 2013]

– Physician-performed duplex US may be useful in the management of patients with suspected DVT.

DVT [Mustafa BO et al 2002]

(upper extremity) – Only one study met all of the predefined criteria for adequately evaluating sens and spec. The sens of duplex ultrasonography ranged from 56% to 100%, and the spec ranged from 94% to 100%.

Pneumonia [Chavez MA et al 2014]

– 10 studies n = 1172. Pooled sens 94%, pooled spec 96%. Lung US when performed by highly skilled sonographers performs well for the diagnosis of pneumonia. It is an established diagnostic tool in the hands of experienced physicians.

Pneumonia [Hu Q-J et al 2014]

– 9 studies n = 1080. Combined sens 97%, spec 94%. Lung US is capable of diagnosing pneumonia with high accuracy. It is a promising attractive alternative to chest radiography and thoracic CT scans.

Pancreatic mass lesions [Puli SR et al 2013]

– 13 studies n = 456. Pooled sens 87%, pooled spec 98%. Contrast-enhanced US is reliable for the differential diagnosis of pancreatic adenocarcinoma. A useful tool in clinical practice. Excellent sens and spec to diagnose and should be strongly considered for evaluation of pancreatic neuroendocrine tumors.

Fetal assessment [Whitworth M et al 2015]

– 11 trials n = 37505 women. US for fetal assessment in early pregnancy reduces the failure to detect multiple pregnancy by 24 weeks' gestation (risk ratio (RR) 0.07). Routine scans improve the detection of major fetal abnormality before 24 weeks' gestation (RR 3.46). Early US improves the early detection of multiple pregnancies and improved gestational dating may result in fewer inductions for postmaturity.

Abdominal aortic aneurysm [Cosford PA et al 2007]

– 4 studies n = 127,891 men and 9,342 women. There was a significant decrease in mortality from AAA in men (OR 0.60) but not for women (OR 1.99). There is evidence of a significant reduction in mortality from AAA in men aged 65 to 79 years who undergo US screening. There is insufficient evidence to demonstrate benefit in women. The cost effectiveness may be acceptable but needs further expert analysis. These findings need careful consideration in judging whether a coordinated population-based screening program should be introduced.

Cholelithiasis [Ross M et al 2011]

– 8 studies n = 710 sens 90%, spec 88%. This study suggests that in patients presenting to the ED with pain consistent with biliary colic, a positive emergency US scan may be used to arrange for appropriate outpatient follow up if symptoms have resolved. In patients with a low pretest probability, a negative emergency US scan should prompt the clinician to consider an alternative diagnosis.

Retinal detachment [Vrablik ME et al 2015]

– 78 studies were selected for full-text review, resulting in 4 trials assessed for quality. Sens ranged from 97-100%, spec ranged from 83-100%. Bedside ocular ultrasonography has a high degree of accuracy in identifying retinal detachment.

Common bile duct stones [Gurusamy KS et al 2015]

– 5 studies n = 523. Average sens 73%, average spec 91%. Many people may have common bile duct stones in spite of having a negative US and false-positive results are also possible. Further studies of high methodological quality are necessary to determine the diagnostic accuracy of US and liver function tests.

Carotid artery stenosis [Jonas DE et al 2014].

– To evaluate evidence on screening and treating asymptomatic adults for CAS.

Given the specificity of ultrasonography (range, 88% to 94% for CAS ≥ 50% to ≥ 70%), its use in low-prevalence populations would yield many false-positive results. Absolute reduction of nonperioperative strokes was 5.5% (95% CI, 3.9% to 7.0%; 3 trials; 5223 participants) over approximately 5 years for CEA compared with medical therapy. Current evidence does not establish incremental overall benefit of CEA, stenting, or intensification of medical therapy. Potential for overall benefit is limited by low prevalence and harms.

**DISCUSSION**

These documents mentioned in the results are just manuscript retrievals from medical databases such as Pubmed or the Cochrane library, whereby ultrasound is a useful diagnostic modality. These are not connected at all with the haptic robotic technology being developed. No organisation that is involved in that setup or trial has reviewed this literature, nor have they reviewed, contributed or endorsed this manuscript. This mere attempt at drawing on literature in order to guide further testing is purely reviewing published manuscripts that are entirely independent. This is for the purpose of deciding on a medical condition whereby ultrasound is the preferred diagnostic test, where there is clearly benefit that outweighs the benefit that may be obtained by early diagnosis of other conditions, in terms of there being treatment alternatives for preventing either morbidity or mortality and with cost savings to the community.

Ultrasound is recommended for the diagnosis of various conditions such as; breast cancer detection, acute maxillary sinusitis, suspected subacromial disorders, juvenile idiopathic arthritis, thyroid lesions / nodules, DVT, cholelithiasis, retinal detachment, carotid artery stenosis, common bile duct stones, appendicitis/ gallstones, pneumonia, pancreatic mass lesions, fetal assessment and for screening to detect abdominal aortic aneurysm.

When deciding upon diagnostic testing various criteria and guidelines must be considered. A test must be valid, whereby clinical validity describes the ability of the test to predict the clinically relevant outcome that is to be controlled or prevented [Bell et al 2014]. Bell and colleagues [Bell et al 2014] also discuss how a test must be practical, which relates to the ease of use, invasiveness and cost of the test. In order to develop a comprehensive and transparent approach for developing clinical recommendations about using diagnostic tests or diagnostic strategies, the GRADE approach can be utilised to grade the quality of evidence and strength of recommendations [Brozek et al 2009]. The GRADE approach, using valid diagnostic accuracy studies provides high quality evidence of test accuracy, but in fact, these studies often provide only low-quality evidence for developing recommendations about diagnostic testing. Having a diagnostic test result that determines a definitive diagnosis is one aspect, but it is also a requirement to consider before implementing diagnostic tests that may involve effort, resources, cost and time, that there are available treatment alternatives should a diagnosis be made. In addition, consideration should be given to whether patient wellbeing could be improved through having a diagnosis, or even that as a result of excluding an ominous diagnosis there may be a reduction of patient anxiousness [Brozek et al 2009].

While a diagnostic test may be recommended for an individual, screening guidelines have other factors to consider in addition to test accuracy, including the prevalence of the disease in the community or target population, whether treatment options are available and if there is evidence related to potential successful outcomes attainable as a result of treatment alternatives [Cancer Council Australia 2018, Wilson JMG and Jungner G 1968]. These references mentioned, state that the disease must be considered an important health problem in the community, there must be an understanding of the natural disease progression and in addition, there should be a recognisable latent or early symptomatic stage. Screening should be carried out when the intervention for those found positive is widely accepted by the scientific and medical community. In addition, the test must be practical, which relates to implementation variables, cost and set up requirements. Community acceptance is also an

important factor for consideration which also incorporates how well the test will draw or net people towards a screening program and whether it appears inviting and acceptable [Wilson JMG and Jungner G 1968] and this may include whether there are adequate facilities [Institute of Medicine (US) Committee on Perinatal Transmission of HIV 1999] or alternatively if facilities or resources are not well organised, or in fact if the process is too cumbersome some people may be turned away or hesitant from attending. In addition, if potential harms outweigh possible benefits, then screening may not be advisable. Cancer Council Australia [2018] mention possible harms one of which may be a false positive test result, where people without the disease undergo follow-up testing that may be uncomfortable, expensive, and, in some cases, potentially harmful.

In order to implement a pilot study of remote ultrasound for screening in order to test the apparatus, the screening program should aim to capture those whom have the most likely chance of benefit in terms of early disease detection. The difficulty with screening programs is that if a group are invited to attend, people who choose to participate in screening programs tend to be healthier and have healthier lifestyles. In addition, people whom attend screening, may also be the worried well, while asymptomatic, may worry about risk more as they have a relative for example with breast cancer and this can bias the screening benefits [LaMorte 2016].

In terms of published research relating to diagnostic screening whereby consideration needs to be given to what medical illness may benefit from treatment being instigated as a result of an earlier diagnostic test, assessing whether there are already published documents in relation to a medical condition is important. Hence if guidelines for utilising the diagnostic test are already in place there may be clear benefit from early diagnosis, and abdominal aortic aneurysm and carotid artery stenosis are conditions whereby numerous documents and recommendations have previously been published.

There are countless documents and guidelines on recommendations that relate to screening for abdominal aortic aneurysm. These include documents such as;

The Australian and New Zealand Society for Vascular Surgery - Aortic Aneurysm Screening.

United States Preventative Services Taskforce - Abdominal Aortic Aneurysm: Screening.

Kaiser Permanente. Abdominal aortic aneurism screening guideline.

Society for Vascular Surgery. Position Statement on Vascular Screening.

Most patients with a ruptured aortic aneurysm will not survive. In contrast screening in order to discover an aortic aneurysm before it bursts decreases the risk of dying from planned surgery to around 3-5% or less [Australian and New Zealand Society for Vascular Surgery 2018].

In men, aged 65-75 years who have ever smoked, the United States Preventative Services (USPS) Taskforce recommends one-time screening for AAA with ultrasonography [United States Preventative Services Taskforce. Abdominal Aortic Aneurysm: Screening [2014]]. For men the same age, whom have never smoked, the recommendations are for selective screening. The guidelines for women whom have smoked state that the evidence is insufficient, while for those whom have not smoked, screening is not recommended. The British Heart Foundation (BHF) by contrast recommends screening for all men over 65 years of age, whereas their advice for women is to talk to their GP if they have concerns or risk factors [British Heart Foundation accessed 2018].

The Kaiser Permanente screening guidelines for abdominal aortic aneurism also as above do not recommend screening for women and this is irrespective of smoking history/ status [as there is insufficient evidence], nor do they recommend screening for men under 65 years of age. In addition, for men, the guidelines are similar in that for current or previous smokers, screening is recommended for those 65-75 years of age, however for those whom have never smoked, screening may be considered for men in that age group, where there are other risk factors [history of vascular aneurysm, coronary artery disease, cerebrovascular disease, atherosclerosis, hypercholesterolemia, obesity, and hypertension] or a family history [Kaiser Permanente 2016].

The Society for Vascular Screening has recommendations that differ somewhat to those above. Their document titled; Position Statement on Vascular Screening recommends screening for all men at or older than 65 years, yet may be considered for those younger where there is a family history of AAA. Women over 65 years of age, whom have a family history of AAA, or whom have smoked are advised to have screening [Society for Vascular Surgery 2011].

While the previous paragraphs detail recommendations for AAA screening, the following paragraphs discuss the guidelines for carotid artery stenosis or atherosclerotic disease.

Jonas and colleagues [Jonas et al 2014] conducted a systematic review on screening for asymptomatic carotid artery stenosis. These reported the specificity of ultrasonography as (range, 88% to 94% for CAS ≥ 50% to ≥ 70%), and hence its use in low-prevalence populations would yield many false-positive results. In addition, the treatment of asymptomatic persons with carotid artery stenosis has the potential for harm which include complications related to treatment with either; carotid endarterectomy, stenting or medical therapy. Possible harm can include stroke, death, myocardial infarction, nerve injury, and hematoma. Also, there is potential for low overall benefit, that relates to the low overall prevalence of the disease.

Aside from this above systematic review on screening for carotid artery stenosis, there are other guidelines or manuscripts as below which also report similar concerns to the above. According to the Agency for Healthcare Research and Quality document titled; Screening for Asymptomatic Carotid Artery Stenosis, screening of asymptomatic patients and subsequent treatment with carotid endarterectomy has an unknown stroke risk reduction. This is due to the low overall prevalence in the asymptomatic population of treatable disease and due to possible harms from treatment [Agency for Healthcare Research and Quality 2007]. RadiologyInfo.org [accessed 24/10/18] state there are joint guidelines that were issued by the American College of Cardiology Foundation, American Heart Association, American Stroke Association and other healthcare groups. This document suggests that carotid duplex US may be considered for asymptomatic patients who have disease such as atherosclerotic aortic aneurysm, peripheral artery disease, coronary artery disease, or at least two risk factors for stroke including either: a first-degree relative with atherosclerosis that developed before age 60, a family history of ischemic stroke, hypertension or hypercholesterolemia. Kang and Weerakkody whom authored the document for Radiopaedia titled; ultrasound assessment of carotid arterial atherosclerotic disease reported that ultrasound assessment of carotid arterial atherosclerotic disease has become the first choice for carotid artery stenosis screening, permitting the evaluation of plaques in the carotid artery as well as flow characteristics [Kang and Weerakkody 2018].

Hall [2008] discusses issues related to ultrasound screening in science and medicine. Quoted in this document is recommendations by the United States Preventative Services Task Force, and they conclude that carotid artery screening is not recommended, but abdominal aortic

aneurysm screening is recommended only once for men between the ages of 65 and 75 who have ever smoked.

In consideration of understanding the systematic reviews related to diagnostic research, there are some methodological flaws that must be taken into account that could influence the results. Reviews of diagnostic test accuracy, require search strategies but they may miss papers in that they are not easily identified as studies of diagnostic test accuracy, and having less information in the abstract makes it difficult to assess systematic review inclusion eligibility [Doust et al 2005]. Some of the methodological challenges that remain with diagnostic research are the poor reporting of original diagnostic test accuracy studies and the difficulties with the interpretation of the results of diagnostic test accuracy research [Leeflang et al 2008]. These factors should be considered when reading the diagnostic reviews. In order to standardise the reporting of diagnostic accuracy, there is a committee titled; The Standards for Reporting of Diagnostic Accuracy (STARD) steering committee [Bossuyt et al 2004]. They conducted a search for published guidelines about diagnostic research and they yielded 33 previously published checklists, with 75 potential items being extracted. At the consensus meeting, this was shortened to a 25-item checklist.

LaMorte [2016] titled a document [screening for disease] and they discuss how in some cases early diagnosis can appear to increase survival time, but it must be taken into account that the length of time from diagnosis to death may appear longer, but this may just be in fact an increased time in that the disease is identified earlier, so treatment also begins earlier, but in fact the point of death is the same and this effect which appears as a longer survival time is known as the ‘lead time bias’.

While the methodological factors related to how a diagnostic review is carried out is one factor to consider, other factors to consider before carrying out screening or implementing a pilot trial relate to disease variables, treatment options and patient preference aspects.

Test Accuracy (TA) is commonly considered by organizations when developing recommendations about health-related tests and diagnostic strategies [HCTDS], but it is not all that is required to be considered, in that if only considered may in fact be misleading [Mustafa et al 2017]. Other identified important factors are consideration of potential care pathways based upon diagnosis, but this is often not considered. Cost, clinical, and

preference decisions are important to consider even in the absence of direct diagnostic test evidence, and decision analysis can be used for this process [Mustafa et al 2017].

## CONCLUSION

In summary, these results are interesting to review. US is an acceptable diagnostic tool for a range of medical conditions that patients may have. Further review of the available literature on diagnostic and screening tests must be done in order to move forward. A diagnosis for an individual may be life saving for that person hence is priceless to that person. If more widespread usage is to occur, considerations to take into account are; whether the disease is an important health problem, the prevalence, the biological behaviour of the disease and whether treatment is available. With respect to the test considerations, these include the sensitivity, specificity, cost, acceptability and safety of the test. Country guidelines and documents already exist in relation to US screening. Experts and specialists in diagnosis and screening should obviously also be consulted. There appears to be a plethora of documents related to abdominal aortic aneurysm diagnostic screening for different risk groups so this may be a possibility for consideration for a pilot study of this novel remote-controlled apparatus. These results are interesting to review before deciding on the future of remote robotic technology developments.



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