The effectiveness of septal ablation versus septal myectomy on survival for patients with hypertrophic cardiomyopathy

Priya Sharma*

Department of Bio medical sciences, University of Hertfordshire, London, United Kingdom

ABSTRACT

Background: Hypertrophic cardiomyopathy is an autosomal dominant condition affecting males and females across all ages and ethnicities. This condition results in the thickening of the heart’s myocardium, leading to reduced cardiac output, with subsequent complications including heart arrhythmias and sudden cardiac death (SCD). Currently, septal myectomy, a type of open heart surgery, continues to be the gold standard treatment for reducing the left ventricular outflow tract (LVOT) obstruction. However, in recent years, septal ablation has emerged as a newer, less invasive procedure which aims to obliterate the obstruction via injection of alcohol into the hypertrophied septum.

Objectives: The aim of this systematic literature review is to establish whether septal myectomy or septal ablation is more effective in prolonging survival in hypertrophic cardiomyopathy patients.

Methodology: The methods used in this research were in accordance to a systematic literature review. The databases: PubMed, Cochrane and Scopus were utilised to extract relevant studies to further analyse and then to critically appraise using CASP tools.

Key Findings: All studies included in this systematic literature review appreciated that the effects of septal myectomy and septal ablation were comparable, to an extent, when assessing clinical outcomes and survival for hypertrophic cardiomyopathy patients.

Conclusion: Despite septal ablation being a more advanced and minimally invasive procedure with optimistic clinical outcomes, septal myectomy remains superior due to its long-term relief from symptoms and increased likelihood of survival.

Keywords: Hypertrophic cardiomyopathy; septal myectomy; septal ablation

INTRODUCTION

Background

Hypertrophic cardiomyopathy is a cardiovascular disease which can affect both males and females across all ages and ethnicities. The condition results in the myocardium of the ventricular walls of the heart becoming hypertrophic due to an increase in the size of myocytes. The myocardium is the middle-layer of the wall of the heart which is collected of cardiac muscle fibres that enable contractility (Bailey, 2017). Patients who suffer from the disease are at risk of several complications, namely heart failure, sudden cardiac death and atrial fibrillation which increases the risk of an embolic stroke (Liew, Vassiliou, Cooper & Raphael, 2017).

Pathophysiology

Hypertrophic cardiomyopathy results in asymmetrical thickening of the myocardium, and a range of patterns of left ventricular wall hypertrophy exist (Maron, 1997). Due to the walls of the ventricles becoming thick/stiff, they do not relax to a sufficient degree, meaning they cannot fill with blood, consequently this reduces cardiac output (Stamos, 2018).

*Corresponding author: Department of Bio medical sciences, University of Hertfordshire, London, United Kingdom, Tel: 07807287574; E-mail: priya_sharma757@gmail.com

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Hypertrophic cardiomyopathy is inherited in an autosomal dominant approach, meaning that one of the alleles is faulty; it is most commonly caused by a mutation in one of 12 genes which encode various thick and thin myofilament constituents of the sarcomere (Davies, 2000). The mutations in hypertrophic cardiomyopathy are linked to a predisposition in the modification of cardiac contractility, and animal studies on mice and rabbits have exhibited that the effects of mutations in genes, which are also present in humans, cause increased fibrosis and hypertrophy of cardiac muscle (Roberts & Sigwart, 2005).

One of the mutations for familial hypertrophic cardiomyopathy is in exon 13 of the beta cardiac myosin heavy chain (Geisterfer-Lowrance et al., 1990). The genes that are most frequently affected are the myosin-binding protein C as well as the α myosin heavy chain (Shah, 2017). Most cases in younger patients are associated with congenital syndromes, metabolic conditions and neuromuscular diseases. In adults, however, having hypertrophic cardiomyopathy is linked to familial diseases (Elliot & McKenna, 2004).

Prevalence

The condition is one of the leading causes of sudden cardiac death, affecting 1 in 500 people (Liew, Vassiliou, Cooper & Raphael, 2017). Many patients who have hypertrophic cardiomyopathy may experience little to no symptoms, others may encounter symptoms including shortness of breath and chest pain (Houston & Stevens, 2014). Current literature does not establish why it is that some patients may remain asymptomatic, however, it is recognised that the disorder has various ways of manifesting itself. The most common type of manifestation is obstructive hypertrophic cardiomyopathy. In obstructive hypertrophic cardiomyopathy, the septal wall is thickened meaning the outflow tract is narrowed by the mitral valve and the heart must impulse with a greater pressure (Liew, Vassiliou, Cooper & Raphael, 2017).

It has been found that patients who have hypertrophic cardiomyopathy usually have an unremarkable physical examination, however there may be the presence of two different types of murmur that are associated with the disease (Houston & Stevens, 2014). One of the murmurs is a systolic ejection murmur. The second murmur is a pansystolic fourth heart sound which is caused by mitral regurgitation (Nickson, 2014).

Investigations

Echocardiography and/or an MRI can be utilised to diagnose hypertrophic cardiomyopathy. A suspected diagnosis can be made if a murmur and the respective symptoms are present, and the suspicion can be raised further if the patient has a family history of sudden death (Stamos, 2018).

Echocardiography is a useful tool to diagnosis; it can measure the severity of the hypertrophy and the grade of left ventricular outflow tract (LVOT) obstruction. Patterns of left ventricular hypertrophy are consistent with the diagnosis of hypertrophic cardiomyopathy; however, most patients display asymmetrical septal hypertrophy (Stamos, 2018).

Subsequent Chapters

The following chapters will include a literature review discussing further information about hypertrophic cardiomyopathy and the justification for carrying out a systematic literature review. Following this, the methods will add to this by covering the theoretical approaches used to obtain research papers, and the rationale for the methods used. Finally, the results and discussion will review the findings acquired from the chosen studies and aim to critically appraise and subsequently evaluate the effectiveness of septal ablation and septal myectomy on survival and clinical outcomes.

LITERATURE REVIEW

Treatments

The goal of treating hypertrophic cardiomyopathy is to obliterate LVOT obstruction. This obstruction can cause symptoms of heart failure and reduce survival. Medical therapy is used as a first-line treatment; beta blockers, for example propanolol are used for symptomatic LVOT obstruction (Jacoby, DePasquale & McKenna, 2012).

If there is initial treatment failure after the use of drugs, and there is sub-aortic obstruction, then the options for treatment are either alcohol septal ablation or septal myectomy (Maron & Nishimura, 2014).

Septal myectomy, which is the current gold standard treatment for hypertrophic cardiomyopathy, is an open-heart surgery where excess muscle from the hypertrophic septum is removed to reduce LVOT obstruction. It is known that patients experience swift relief from their symptoms post-procedure (“Septal Myectomy | Johns Hopkins Medicine Health Library”, n.d.). Despite the benefits of septal myectomy, there are some drawbacks, including the fact that patients who are elderly or have multiple co-morbidities are not eligible for the treatment due to peri-procedural risks, such as infection and arrhythmias (“Septal Myectomy | Cleveland Clinic”, 2019). Due to these reasons, septal ablation, a newer treatment used to eradicate the LVOT obstruction can be employed in its place.

Septal ablation, which was originally introduced in 1994, is a negligibly invasive modality for the treatment of hypertrophic obstructive cardiomyopathy. The procedure works by injecting alcohol into the septal perforator which allows for an infarction of the hypertrophic septum to take place, this reduces the thickening of the septum and eliminates the LVOT obstruction. Similar to septal myectomy, there are complications associated with this procedure, for example heart blocks, and the need for reintervention (Masry & Breall, 2008).

Objectives

The topic of establishing whether septal ablation is superior than septal myectomy in treating hypertrophic cardiomyopathy is important as there has been rising debate about whether septal ablation can surpass the current gold standard treatment of septal myectomy. Present guidelines state that surgical myectomy is the preferred procedure for reduction of septal thickening for patients who have the most severe symptoms of...
hypertrophic cardiomyopathy due to its rapid effectiveness and safety (Maron & Nishimura, 2014).

The focus of this study is to explore the named treatment methods for obstructive hypertrophic cardiomyopathy in terms of their effectiveness in relation to survival. Currently, there has not been an extensive amount of research in this area, hence why it is important to study this further to ascertain the efficacy of both treatments.

**Research justification**

Research regarding this area is imperative as, in recent years, there have been numerous debates relating to whether septal ablation being the newer technique is superior to the gold standard septal myectomy. In finding out which is better, it can be established which treatment will be more effective, and which one will have a more positive long standing outcome in terms of clinical symptoms and survival (Maron & Nishimura, 2014). This research is important for the physician associate role as hypertrophic myopathy is a part of the physician associate matrix, and so having knowledge about which treatment is better is vital for so that patient satisfaction and wellbeing can be implemented.

**METHODS**

A systematic literature review was selected as opposed to other research methodologies such as audits and surveys due to time constraints, and a systematic literature review permits the collation of results from different studies, so they can produce a universal conclusion. It also allows for the reader to replicate the searches that were carried out from databases.

**Search Strategy**

Initially, a research question was articulated using the PICO (population, intervention, comparator and outcome) framework. The PICO terms based on the research question were ‘hypertrophic cardiomyopathy’, ‘septal ablation’, ‘septal myectomy’ and ‘effectiveness on survival’, respectively.

After formulating the research question, databases where the searches would be carried out were then selected, these databases were: PubMed, Cochrane and Scopus. These three databases were chosen as they are well-known and contain a wide range of available clinical and cardiovascular literature on the topic which would help to answer the question. All three databases allow for the reader to pick certain inclusion and exclusion criteria which mean that there are more accurate and specific search results.

The MeSH (medical subject headings) search was then conducted. A MeSH search is a way of searching synonyms or alternate forms of individual terms or phrases in a question. In this systematic review, it applied to the individual PICO terms. The results of the MeSH search can be seen in (Table 1).

**Table 1: MeSH terms obtained from a PubMed MeSH search**

<table>
<thead>
<tr>
<th>Population</th>
<th>Intervention</th>
<th>Comparator</th>
<th>Outcome</th>
</tr>
</thead>
<tbody>
<tr>
<td>Patients with hypertrophic cardiomyopathy</td>
<td>Septal ablation</td>
<td>Septal myectomy</td>
<td>Effectiveness on survival</td>
</tr>
<tr>
<td>Hypertrophic cardiomyopathy</td>
<td>· Septal ablation</td>
<td>· Septal myectomy</td>
<td>· Effectiveness on survival</td>
</tr>
<tr>
<td>Cardiomyopathies, hypertrophic</td>
<td>· Alcohol septal ablation</td>
<td>· Myectomy, septal</td>
<td></td>
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<tr>
<td>Hypertrophic cardiomyopathies</td>
<td>· Ablation, septal</td>
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<tr>
<td>Cardiomyopathy, hypertrophic</td>
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<td>Cardiomyopathies, hypertrophic</td>
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<td>Obstructive Cardiomyopathy, Hypertrophic</td>
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</table>

The next stage of the systematic review was to conduct a Boolean search from the MeSH terms that had been obtained. A Boolean search is a type of advanced search which allows for the combination of keywords with the use of operators such as ‘AND’ and ‘OR’ to broaden relevant search results and to make them more specific to the topic of interest. The Boolean search terms and number of results across all the chosen databases can be seen in Appendix A.

**Inclusion and Exclusion Criteria**

Once the keywords had all been combined using the Boolean operators and the search results had been obtained, limitations/inclusion criteria and exclusion criteria available on the
databases, as seen in Table 2, were set to narrow down the results further to make them more specific to the relevant treatments for hypertrophic cardiomyopathy.

**Table 2: Inclusion criteria/limitations and exclusion criteria**

<table>
<thead>
<tr>
<th>Inclusion criteria/Limitations</th>
<th>Exclusion criteria</th>
</tr>
</thead>
<tbody>
<tr>
<td>· Clinical trials</td>
<td>· Systematic reviews</td>
</tr>
<tr>
<td>· Clinical studies</td>
<td>· Meta-analyses</td>
</tr>
<tr>
<td>· Comparative studies</td>
<td>· Articles not in English</td>
</tr>
<tr>
<td>· Controlled clinical trials</td>
<td>· Articles older than 10 years (older than 2009)</td>
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<td>· Multicentre studies</td>
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<td>· Observational studies</td>
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<tr>
<td>· Pragmatic clinical trials</td>
<td></td>
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<tr>
<td>· Human species</td>
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<tr>
<td>· English language</td>
<td></td>
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<tr>
<td>· Articles published within the last 10 years (2009-2019)</td>
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</table>

**Critical Appraisal**

Finally, after finalising the papers that would be used as part of the systematic review, they needed to be critically appraised. Critical appraisal was carried out using CASP tools; this permitted systematic examination of the chosen studies to evaluate their validity and assess their outcome for the clinical topic.

**Risk and Ethical Considerations**

No ethical approval was needed as the authors in the studies analysed in this systematic literature review obtained informed consent from their participants.

**DISCUSSION**

**Rationale**

This systematic literature review aimed to explore the effectiveness of septal ablation versus septal myectomy in relation to survival for patients suffering with hypertrophic cardiomyopathy, in order to establish which treatment would be better for prolonging the life of patients. A systematic literature review on this topic is important as there is a lack of ample literature comparing the effectiveness of septal ablation and septal myectomy on survival. Collating this information from different studies would be beneficial to both healthcare professionals and patients; healthcare professionals such as doctors and physician associates would profit from this evidence as it would aid them in deciding which treatment would be better suited to individual patients to maintain patient-centred care. This information can then be relayed onto patients to help them remain autonomous when choosing their desired treatment.

**Main Findings**

All three papers could come to a generalised conclusion based on their results. Studies A and C analysed the LVOT gradient before and after both treatments (Figure 5 shows the LVOT gradient measured in study A). As seen in Table 3, the gradient in both studies was lowest after septal myectomy (10 mm Hg post-procedure in study A, and 13.95 +/- 9.94 mm Hg post-procedure in study C). A high LVOT gradient results in greater obstruction, and has been correlated with an amplified risk of sudden cardiac death (SCD), severe heart failure and a lower survival rate (Liew, Vassiliou, Cooper & Raphael, 2017). This can be supported by a single-center study which found that septal ablation had a higher rate of sudden cardiac death (ten Cate et al., 2010). On the other hand, a study by Spaziano, Sawaya and Lefivre (2017) showed that the 5 and 10-year survival rate for septal ablation was 94.1% and 86.9%, respectively, which is analogous to the septal myectomy 5 and 10-year survival rates shown in Figure 3 of 92% and 85%, respectively.

The studies investigated mortality rates after follow-up, cardiac death was higher after myectomy compared to ablation in study A, seen in Figure 2, at 1.4%, conversely study C found late mortality after myectomy was lower than ablation, seen in Figure 4, at 1.27% and 1.47%, respectively. The rate of annual SCD in study B was measured, and found myectomy to have a lower frequency at 0.8% per year. This figure is considerably lower than the rate of annual SCD without treatment, which a study conducted in 2007 found to be 4.3% in a non-myectomy group (McLeod et al., 2007).
In terms of assessing mortality/survival alone, all the studies highlighted that both septal ablation and septal myectomy were mostly comparable with the mortality and survival rates being similar. To support this, current literature has discovered that post-procedural and late mortality rates between both treatment groups are low, however septal ablation has required a higher need for re-intervention due to complications (Poon, Field, Gupta & Cameron, 2017).

**Significance and Implications**

The results from the studies are significant to the extent that they reinforce what is currently known about the area. The focus of this systematic literature review is on which treatment would be more effective in relation to survival, and other studies have found that long-term SCD and mortality rates were comparable. Another aspect which has been strengthened is that ablation remains secondary to myectomy due to the increasing need for intervention post-procedure (Liebregts, Vriesendorp & ten Berg, 2017).

The results can be implicated in practice as the evidence demonstrates that both treatments are effective in relieving the outflow tract obstruction, and subsequently improving survival, however myectomy improves the LVOT gradient the greatest and so will remain the preferred treatment. However, septal myectomy requires great surgical knowledge and so is not widely available in all centres, and so patients would benefit from knowing about the advantages of septal ablation.

**Limitations**

Sample size plays a vast factor in assessing the reliability and representability of the results. The sample sizes in the three papers were small (seen in Table 3) considering that the condition affects 1 in 500 people in the entire population. The sample sizes for the papers were in the hundreds, meaning the results may not have been as precise and generalizable to the population (Biau, Kernéis & Porcher, 2008). A larger sample size (at least over a thousand patients) would have solved this problem.

Table 3 also highlights the follow-up periods across the studies; study A had a respectable period of 11 years, however studies B and C had a shorter follow-up duration meaning the results may not have been complete enough to apply into practice. A longer duration would increase the usefulness of the research, and review any new changes (Salkind, 2010).

Despite the limitations, the CASP summary in Table 4 displays that studies A and B were of good quality, whereas study C was satisfactory.

Additionally, a limitation in this systematic review included a lack of searches on various databases; only three databases were used to search literature. Using more databases such as PubMed and Cochrane in this systematic review would be strength as they contain a wide range of literature and have several inclusion and exclusion criteria, which help to narrow down the results to make them specific to the topic.

**Further research**

Added studies, similar to the ones analysed in this systematic review, would have to take place to make the results more reliable and representative, and this reliability could be elevated by having larger sample sizes in future observational studies. Additional research being carried out in England would also be valuable as having knowledge about the outcomes from studies in this country would increase the applicability of the results in the NHS.

**RESULTS**

**Screening and Data Extraction**

Results from the searches were screened to check for their eligibility in the systematic review. The screening of the results can be seen in the PRISMA flow diagram in Figure 1.

**Summary of Studies**

The methodology and results across all the studies chosen for this systematic review were analysed and have been summarised in Table 3 below. A total of three papers were chosen for this systematic literature review.

Table 3: Summary of papers identified
STUDY A

Non-randomised, observational study.

Procedures were executed between 1981 and 2010 on a total of 263 patients (161 had alcohol septal ablation and 102 had septal myectomy).

Patients that were selected needed to have severe symptoms (with a New York Heart Association functional class greater than, or equal to 3) even though they were currently on ideal medical therapy.

It was aimed for the baseline characteristics of the subjects to be similar.

47 males and 55 females were chosen for the myectomy group, and 85 males and 76 females were chosen for the ablation group. Ages of the patients for the myectomy group were 56 years +/- 16 years, and for the ablation group they were 59 years +/- 14 years.

Alcohol septal ablation and septal myectomy were performed on the selected patients, left ventricular outflow tract (LVOT) obstruction was determined straight after the procedures.

The maximum follow up period was 11 years to govern long-term clinical outcome and mortality after ablation and myectomy.

STUDY B

Non-randomised observational cohort study.

Procedures were carried out from 1999 onwards on a total of 1047 patients, however only 690 had left ventricular outflow tract gradients that were greater than 30 mm Hg, 124 of these were treated with drugs, 321 had alcohol septal ablation and 253 had septal myectomy, this systematic review will focus on only those who had ablation and myectomy.

Graphs Reflecting Survival

Figure 2: Percentage of annual cardiac death and periprocedural death after septal ablation and septal myectomy from Study A

The methods across all three studies were very similar; as expected with this type of condition and its treatments, they were all non-randomised, observational studies. Studies A and B carried out the procedures many years ago compared with study C which carried out the treatments recently from 2011 to 2015, meaning there could have been differences in how the treatments were performed, affecting the results. All studies had a set of baseline characteristics for the patients that they were going to include, studies A and B chose a similar number of males and females, study C had more males in the study overall and so more male patients were allocated to both septal ablation and septal myectomy. Across all three studies, the age groups for septal ablation were higher than those for septal myectomy, this may have affected the survival rates and clinical outcomes. The sample sizes for studies A and C were relatively reasonable at 263 patients and 226 patients, respectively, however study B had a far superior sample size at 574 patients for the ablation and myectomy groups.
death and periprocedural death was lower in alcohol septal ablation, with 0.7% and 1.2%, respectively.

Figure 3: Percentage of 5-year survival and 10-year survival rates after septal ablation and septal myectomy from Study B

Figure 3 depicts the differences between 5 and 10-year survival rates after undergoing each of the treatments; it can be seen that septal ablation and septal myectomy had similar 5-year survival rates, at 91% and 92%, respectively. The 10-year survival rates for the treatments did contrast slightly, with septal myectomy having a slightly higher percentage at 85% compared to septal ablation which had a percentage of survival of 82%.

Figure 4: Percentage of post procedure mortality and late mortality after septal ablation and septal myectomy from Study C

Figure 4 illustrates the differentiation between post-procedure and late mortality, post-procedural mortality was higher in septal ablation at 2.94% compared to septal myectomy which had a mortality rate of 1.27%. Late mortality reduced at 1.47% for septal ablation and stayed the same at 1.27% for septal myectomy, consistently being lower than ablation.

Above, Figure 5 represents the comparisons of the median measurements of LVOT gradients before and after the treatments. Before the treatments, the median LVOT gradient of the septal ablation group was 32 mm Hg, and the LVOT gradient for the septal myectomy group was 50 mm Hg. After being exposed to the treatment, the LVOT gradient in the septal ablation group reduced by 22 mm Hg, going down to 10 mm Hg, and the gradient in the septal myectomy group dropped the greatest, by 41 mm Hg, going down to 9 mm Hg.

Table 4: Summary of results from CASP critical appraisal in studies A, B and C

<table>
<thead>
<tr>
<th>Question</th>
<th>STUDY A</th>
<th>STUDY B</th>
<th>STUDY C</th>
</tr>
</thead>
<tbody>
<tr>
<td>Did the study address a clearly focused issue?</td>
<td>YES</td>
<td>YES</td>
<td>YES</td>
</tr>
<tr>
<td>Was the cohort recruited in an acceptable way?</td>
<td>YES</td>
<td>CAN’T TELL - only patients from tertiary referral centers</td>
<td>YES used</td>
</tr>
<tr>
<td>Was the exposure accurately measures to minimize bias?</td>
<td>YES</td>
<td>YES</td>
<td>YES</td>
</tr>
</tbody>
</table>
Was the outcome accurately measured to minimize bias? CAN’T TELL – difference in follow-up years for each treatment YES YES

(a) Have all the authors identified all important confounding factors? YES YES YES

(b) Have they taken account of the confounding factors in the design and/or analysis? YES YES

(a) Was the follow up of subjects complete enough? YES YES NO – follow-up was not long enough for effects to show

(b) Was the follow up of subjects long enough? YES CAN’T TELL – mean duration was 7.5 years – could be longer NO – duration not long enough

How precise are the results? Precise - confidence interval is 95% Precise - confidence interval is 95% CAN’T TELL – no confidence interval given

Do you believe the results? YES YES CAN’T TELL – the results are not complete enough due to short follow-up

Can the results be applied to the local population? YES YES YES

Do the results of this study fit with other available evidence? YES YES YES

Does the study have implications for practice? YES YES YES

Critical Appraisal Summary

For this systematic review, all the studies were of an observational/cohort nature and so the cohort study CASP tool was utilised (the complete CASP tool results can be seen in Appendix B).

In general, all papers were of good quality as they can have implications in practice and be applied to the local population. Study A was superior than the others, study B was a good paper with the only drawbacks being the duration of the follow-up period and the slight bias from patients being recruited from tertiary referral centres. Study C was the weakest with the shortest follow-up period, meaning the results would not have been as reliable as the results from studies A and B. The confidence interval was also not provided in study C, meaning the precision of the results could not be assessed. Therefore, studies A and B were of good quality, and study C was of satisfactory quality.

CONCLUSION

A systematic literature review was performed to ascertain the effectiveness in relation to survival of septal ablation versus septal myectomy on patients with hypertrophic cardiomyopathy. PubMed, Cochrane and Scopus were the selected databases utilised for the literature searches, from which three studies were chosen and further explored.

Analysis of the literature determined that both septal ablation and septal myectomy yield positive clinical outcomes in terms of improving survival rates in patients with hypertrophic cardiomyopathy. Nevertheless, it is recognised that septal myectomy will remain the gold standard treatment due to its rapidity in liberating symptoms and greater clinical outcomes in comparison with septal ablation. The findings of this systematic literature review may be implemented in practice and used in further research. Though, considering that septal ablation is a relatively new treatment and has not been applied in practice to the extent that septal myectomy has, further research is required to solidify this debate.

REFERENCES


25. Vriesendorp, P., Liebregts, M., Steggerda, R., Schinkel, A., Willems, R., & ten Cate, F. et al. (2014). Long-Term Outcomes After Medical and Invasive Treatment in Patients With Hypertrophic Cardiomyopathy. JACC: Heart Failure, 2(6), 630-636. doi: 10.1016/j.jchf.2014.06.012