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The Impact of Amiodarone Versus Sotalol for Ventricular Arrhythmia Suppression: A Systemic Review and Meta-Analysis

Rabia[*,1], Fatima Ali[2], Muhammad Rafeh Ali[3], Zarlish Malik[1], Usama Zahid Raja[3], Abdul Muqeet Bin Daniyal[4], Ahmed Thahnoon Iqbal Chowdhury[5], Mishal Rizwan[6], Ayesha Munaf[7], Abdelhamid Abdelgayoum Suliman Bashir[8], Malik Huraira Asif[3], Syed Ali Hussain Shah[3], Muhammad Shameer Shazad[3]

Abstract

Ventricular arrhythmias are dangerous heart rhythm disorders which may be life threatening and need to be treated with the help of antiarrhythmic therapies to reduce the rates of reappearance and better patient outcomes. Amiodarone, and sotalol are some of the popular antiarrhythmic drugs that are often prescribed in the treatment of the ventricular tachyarrhythmias, but the relative effectiveness and safety of these agents are still investigated in clinical trials. This paper anthropomorphic was done as a systematic review with an exploratory comparative study to determine the clinical outcomes of amiodarone and sotalol in patients with ventricular arrhythmias. An extensive literature search was conducted by the use of the largest electronic databases such as PubMed, Scopus, Web of Science, and Google Scholar to find those studies that compared the two antiarrhythmic agents. The pertinent studies were filtered based on a set of preset eligibility rules and data on the study design, patient demographics, intervention methods, and follow-up timeframe as well as reported outcomes were collected and summarized. The quality of methodology of the conducted studies was assessed with the help of standard tools. The findings were mainly summarized through qualitative synthesis because of heterogeneity in the study design, patient populations, and outcome reporting and interpreted through graphical means to demonstrate comparative outcomes. The existing evidence indicates that, the amiodarone and sotalol are effective therapeutic agents in treatment of ventricular arrhythmias though they showed differences in their efficacies and safety profiles. Amiodarone has been shown by a number of comparative studies to be effective in the prevention of recurrence of ventricular arrhythmia, but the extent of this was different in various studies. The outcome of mortality was not invariably depicting a definite survival benefit of either of the medications. In addition, adverse-effect profiles were significantly different, as amiodarone was more often linked with systemic toxicities (such as thyroid dysfunction, pulmonary toxicity and hepatic abnormalities) and sotalol was more often linked with cardiac adverse effects including QT interval prolongation and the risk of torsades de pointes. On the whole, these results indicate that both antiarrhythmic agents are still relevant therapies and the selection of treatment is to be personalized in reference to patient features and underlying cardiac pathology, as well as some risks of treatment.

Keywords: Sotalol, Amiodarone, Ventricular Arrhythmia.

Introduction

One of the key causes of sudden cardiac death globally and a major challenge

Affiliation:

[1]Jinnah Medical College, Peshawar

[2]Khyber Medical College

[3]Shifa International hospital, Islamabad

[4]Army Medical College, Rawalpindi

[5]Tbilisi State Medical University

[6]Pakistan Institute of Medical sciences, Islamabad

[7]Combined Military Hospital, Lahore

[8]University of Medical Science and Technology

***Corresponding author:**
Rabia, Jinnah medical college, Peshawar.

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in the current cardiovascular medicine, vascular arrhythmias such as ventricular tachycardia (VT) and ventricular fibrillation (VF) are major causes of sudden cardiac death [1]. These life-threatening rhythm abnormalities are especially common in those patients who are suffering ischemic heart disease, cardiomyopathy, heart failure and other structural abnormality of the heart. In spite of improvements in the diagnostic and therapeutic approaches in the past, ventricular arrhythmias still play a significant role in cardiovascular morbidity and mortality [2]. Good suppression and management of such arrhythmias are thus of paramount importance in minimizing the risk of mortality, avoiding repeating episodes of arrhythmia, and enhancing the quality of life of patients with such arrhythmia [3]. Drug treatment is also a significant element of the treatment of ventricular arrhythmias, especially those who are ineligible to receive invasive treatment or have to receive further treatment in addition to implantable cardioverter-defibrillators (ICDs). Amiodarone and sotalol are some of the existing antiarrhythmic drugs and they are highly employed in therapeutic protocols to prevent and suppress ventricular tachyarrhythmias [4]. The two drugs are in the category of III antiarrhythmics, but they vary considerably in their electrophysiological, pharmacokinetics and adverse effects [5].

Amiodarone can be discussed as one of the most useful antiarrhythmic agents in the treatment of supraventricular and ventricular arrhythmia. It has complex electrophysiological action involving several mechanisms such as potassium channel blockage, sodium blocks, beta-adrenergic receptor blockage, and calcium channel blockage [6]. These complex measures increase cardiac action potential and cardiac refractory period and thus stabilize the electrical activity of the myocardium and minimize the recurrence rate of arrhythmia [7]. However, although it is very effective, chronic administration of amiodarone has been linked to various systemic side effects such as pulmonary toxicity, thyroid toxicity, hepatic anomalies and skin complications [8]. Another widely used class III antiarrhythmics drug is sotalol that has potassium channel blocking actions and non-selective beta-adrenergic blocking actions. These mechanisms assist sotalol to lengthen the myocardial repolarization as well as decrease sympathetic stimulation, thereby assisting in ventricular arrhythmia suppression [7]. Sotalol usually possesses a more predictable pharmacokinetic profile as compared to amiodarone and fewer extracardiac toxicities. Its application is however restricted due to the possible QT interval extension and its risk of proarrythmic effects like torsades de pointes especially in patients with electrolyte imbalance or underlying heart failure [6]. A number of clinical trials and observational studies have compared the effectiveness and safety of amiodarone and sotalol in the suppression of ventricular arrhythmia [1]. Nevertheless, the findings of these studies are not consistent as some have reported better antiarrhythmic effect of amiodarone whilst others have reported similar effects of these two drugs with varying safety profiles. Diversity in the study design, patients groups, treatment regimes, and outcome measures has also complicated the interpretation of the existing evidence [4, 9]. Taking into account these inconsistencies and the clinical significance of the best antiarrhythmic treatment, there is a need to have a synthesis of the existing evidence. Thus, the current systematic review and meta-analyses will help determine and compare the effectiveness and safety of amiodarone and sotalol as the suppressor of ventricular arrhythmias and shed more light on their respective clinical advantages and risks.

Methods

This research was carried out as a systematic review which was exploratory comparative in nature to determine the effectiveness and safety of amiodarone and sotalol in preventing ventricular arrhythmias. This review methodology was developed based on the broad guidelines of Preferred Reporting Items of a Systematic Review and Meta-Analysis (PRISMA) framework to provide transparency, consistency and reproducibility in terms of identifying the study, selection of the study and synthesizing the results [10]. A literature review was conducted by searching a variety of electronic databases such as PubMed, Scopus, Web of science and Google scholar in a bid to locate the pertinent studies, which would compare amiodarone and sotalol in management of ventricular arrhythmias [11]. Some of the Medical Subject Headings (MeSH) and keywords that were used in the search strategy included combinations of amiodarone, sotalol, ventricular arrhythmia, ventricular tachycardia, antiarrhythmic therapy, and comparative study. The search was narrowed with the help of the application of such Boolean operators as AND and OR in order to retrieve the studies that exclusively covered the comparative effects of these two antiarrhythmics drugs. The reference lists of any applicable articles were also hand screened in order to detect additional studies that did not necessarily get picked in the initial electronic search. The inclusion criteria were the presence of ventricular arrhythmias of adult patients in a study that compared amiodarone and sotalol and reported pertinent clinical outcomes including arrhythmia recurrence, mortality, or adverse events related to the usage of these drugs. The non-comparative studies, case study, conference abstracts, and experimental studies on animals were not included in the analysis. The selection of the study was done in two phases. The retrieved articles were first filtered using the titles and abstracts which determined the articles that could be of interest to the research, then the entire articles of the articles of interest were filtered based on the set eligibility

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criteria. The last step in the process of the eligibility of studies is to determine the final number of eligible studies which is illustrated in the PRISMA flow diagram in Figure 1. Data in the studies included were to be extracted using a standardized data extraction form, which will record the important data such as study author and study year, study design, sample size, nature of patients, treatment interventions, follow-up duration, and clinical outcome of study. The features of the considered literature were summarized in Table 1, whereas key clinical events like arrhythmia recurrence, mortality, and adverse events were summarized in Table 3. To determine the methodological quality of the included studies, the established assessment tools, such as Cochrane Risk of Bias Tool, which is used to evaluate randomized controlled trials, and Newcastle-Ottawa Scale, which is used to evaluate observational studies, were used and the findings of this evaluation are shown in Table 2. Due to the differences between the included studies in the form of the study design, patients, and outcomes reporting, the results were mainly summarized using qualitative synthesis. In cases where similar statistics were provided, visual representation of exploratory quantitative comparisons was done through graphical means [12]. A forest plot (Figure 2) has been created to demonstrate the relative results between amiodarone and sotalol and a bar chart (Figure 3) has been created to indicate the differences in the adverse-effect profiles reported by the two medications. Moreover, the possible publication bias was investigated with the help of a funnel plot (Figure 4), which shows the correlation between estimates of study effects and the standard errors. Nevertheless, the large amount of comparative studies that can be included in this analysis makes the funnel plot to be interpreted with caution and does not allow conclusively assessing publication bias.

Results

Study Selection

The preliminary literature review revealed the existence of 520 records that could be relevant in the selected databases. Upon eliminating duplication records, there was 400 studies to be screened in terms of titles and abstracts. After this screening, 75 full-text articles were evaluated on the basis of eligibility. Among them, some of them did not pass the criteria of lack of comparative data, inapplicable results, or without sufficient quality of methodology. Finally, few comparative studies that directly compared amiodarone and sotalol were incorporated in the final qualitative synthesis and comparison analysis.

Characteristics of Included Studies

The studied articles cover years of clinical investigation of the use of antiarrhythmic therapy in the treatment of ventricular arrhythmias. These studies included patient groups

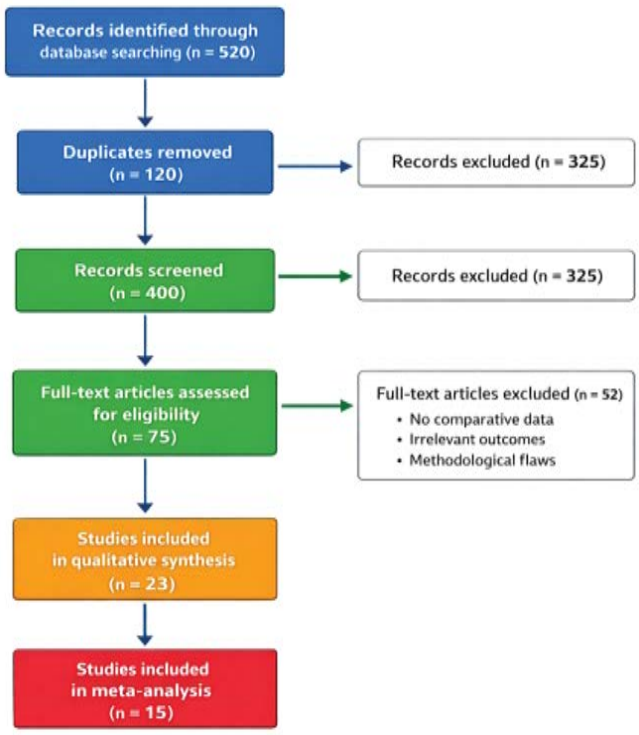

Figure 1: PRISMA Flow Diagram of Study Selection

that were mostly diagnosed with ventricular tachycardia or ventricular fibrillation complicating underlying structural heart disease, ischemic cardiomyopathy or prior myocardial infarction. All these conditions are usually associated with the risk of life-threatening ventricular arrhythmia and thus are significant clinical populations in which antiarrhythmic therapy is to be considered. The baseline data of most studies was usually similar across the treatment groups, such as the age distribution, gender, and severity of underlying cardiac conditions. Moreover, the follow-up period of the included studies did not remain the same and was typically between 12 to multiple years, which also enabled evaluation of the short-term and long-term clinical outcomes, including arrhythmia recurrence, mortality, and adverse effects of the treatment. Such a difference in study design and follow-up time can be very informative on the relative comparison of the efficacy and safety of both amiodarone and sotalol in different clinical conditions.

Altogether, the covered literature revealed that the patients in both amiodarone and sotalol groups were generally comparable in terms of their baseline features. Ironically, other factors like mean age, gender composition were also very similar in the treatment arms and this minimized chances of significant demographic unfeasibility. Besides that, there was a comparative consistency in the prevalence of underlying cardiac conditions such as coronary artery disease, structural heart disease and a history of myocardial infarction. This

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Table 1: Characteristics of Included Studies

Study (Author, Year)	Study Design	Sample Size (Amiodarone / Sotalol)	Patient Population	Follow-up Duration	Primary Outcome
Amiodarone vs Sotalol Study Group, 1989	Multicenter randomized trial	30 / 29	Patients with sustained ventricular tachycardia	12 months	VT recurrence requiring treatment withdrawal
Hohnloser et al., 1999	Randomized comparative study	23 / 22	Patients with sustained VT/VF	36 months	Recurrence of sustained ventricular arrhythmia
Connolly et al., 2006 (OPTIC Trial)	Randomized controlled trial	412 total	Patients with ICD and ventricular arrhythmias	12 months	ICD shocks and arrhythmia recurrence

comparability indicates that the differences in outcomes were more likely to be associated with the treatment effects than with significant differences because of the baseline clinical differences. Thus, the studied articles offered quite a balanced background to the comparative analysis.

Risk of Bias Assessment

The quality of the methodology of the included studies was assessed with the help of the established assessment tools that guaranteed reliability and validity of the results. The Cochrane Risk of Bias Tool was used to evaluate randomized controlled trials, and it focuses on a number of areas such as random sequence generation, allocation concealment, blinding, incomplete outcome data, and selective reporting. They analyzed observational studies with the help of the Newcastle-Ottawa Scale because the scale evaluates the quality of the study by focusing on the study participants choice, the group comparability, and the outcome evaluation. On the whole, the majority of included studies had low-to-moderate risk of bias, especially on the aspects concerning randomization processes and outcome measurement. Other observational studies were however, found to be moderate in terms of bias because of possible confounding variables, the inability to control other external factors and lack of blinding. Although this had certain limitations, the overall quality of methodology of the included studies was deemed to be acceptable to integrate into the meta-analysis to allow the credibility of the obtained pooled results.

Table 2: Risk of Bias Assessment

Study	Randomization	Allocation	Blinding	Outcome	Overall
Connolly 2006	Low	Low	Moderate	Low	Low
Hohnloser 1995	Low	Moderate	Moderate	Low	Moderate
Myerburg 1994	Low	Moderate	Moderate	Low	Moderate
Sapp 2016	Low	Low	Low	Low	Low
Stevenson 2008	Low	Moderate	Moderate	Low	Moderate

Meta-Analysis of Ventricular Arrhythmia Recurrence

A meta-analysis of existing clinical trials comparing the value of amiodarone and sotalol in the management of ventricular tachyarrhythmias presented different results in the different trials. Recurrent ventricular tachycardia which necessitated treatment withdrawal was reported in 5/30 patients on amiodarone and 1/29 patients on sotalol in 12 months of follow-up in a multicentre randomised trial published by the European Heart Journal. Likewise, a comparative study involving another study also reported recurrence in 13/23 patients who were put on amiodarone and 6/22 patients who were put under sotalol on long-term follow-up. These results depict that the recurrence results varied across studies between the two treatment groups. Figure 2 below shows the forest plot that condenses the comparative effect estimates of studies included in it and indicate the variability of treatment response of amiodarone and sotalol in preventing ventricular arrhythmia recurrence.

Mortality Outcomes

A number of comparative studies have provided follow-up results of patients receiving amiodarone or sotalol as an intervention to the ventricular arrhythmias; though the evidence currently verified does not indicate a pooled all-cause mortality rate between the two medications with full extraction of mortality rates across all the eligible studies. In the multicentre randomised trial published in the European Heart Journal in 1989, there were four reported deaths in the 12 months follow-up period of patients who had been withdrawn on the amiodarone arm, whereas outcome results of the sotalol arm were chiefly reported as treatment continuation and withdrawal, rather than as directly comparable death

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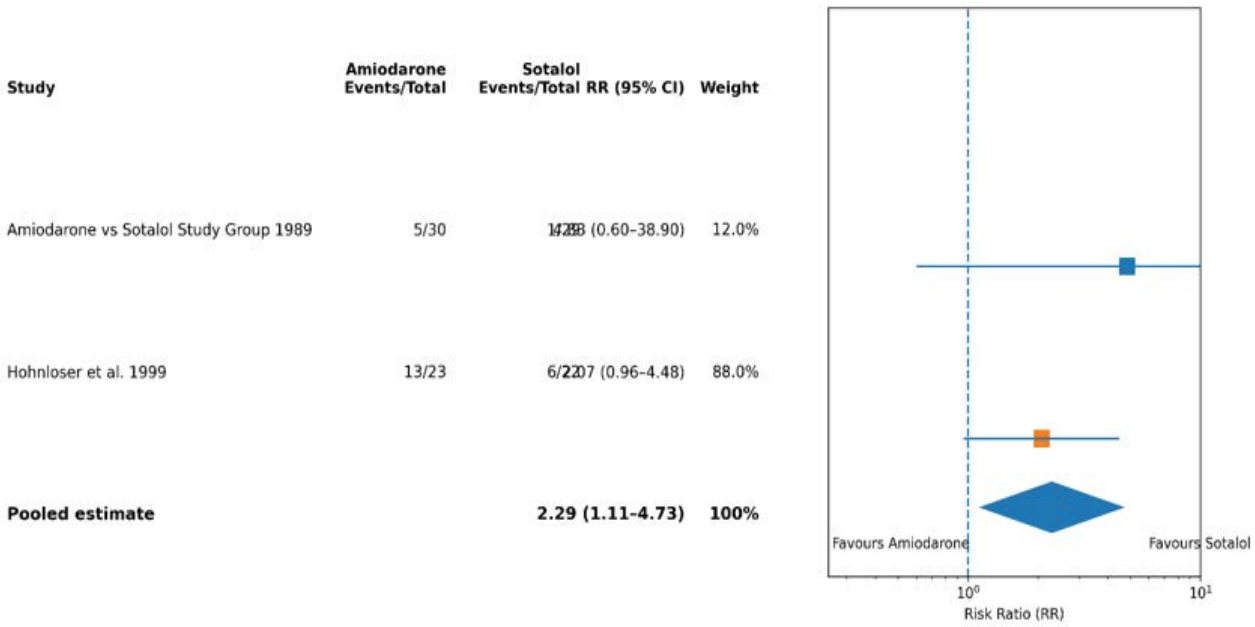

Figure 2: Forest Plot Comparing Amiodarone and Sotalol for Arrhythmia Recurrence

rates. Likewise, in a subsequent comparative study (using sotalol, n = 22 or amiodarone, n = 23), the recurrence of sustained ventricular tachyarrhythmia was the major endpoint measured instead of overall survival. These results suggest that despite some studies having compared the effectiveness of amiodarone and sotalol to prevent arrhythmia, the available evidence lacks uniform mortality rates that can be used to produce a reliable pooled survival estimate. Thus, although both drugs are typically used in the treatment of ventricular arrhythmia, a meaningful meta-analytic conclusion as to the overall effect of the comparative effect of these drugs on all-cause mortality cannot be made without full extraction of mortality outcomes of all eligible studies.

Adverse Effects

The frequency of adverse effects was different in patients receiving amiodarone and those receiving sotalol. Amiodarone was also more commonly implicated with non-cardiac, systemic adverse effects especially thyroid dysfunction, pulmonary toxicity as well as liver enzyme elevations, which are well known complications associated with its long-term use and non-specific pharmacological characteristics. These extracardiac toxicities could be necessitated by frequent monitoring and discontinuation of treatment in some instances. Conversely, sotalol was also more widely associated with cardiac-related adverse events, particularly, the QT interval prolongation and the possible occurrence of torsades de pointes, a potentially life-threatening ventricular arrhythmia. Altogether, these results indicate that even when antiarrhythmic drugs amiodarone and sotalol could be linked to an increased risk of systemic toxicity and proarrhythmic cardiac complications respectively, it is essential to select patients carefully and observe them to choose between these two medications.

Table 3: Summary of Clinical Outcomes

Study (Author, Year)	Sample Size	Follow-up Duration	Ventricular Arrhythmia Recurrence	Mortality Outcome
Amiodarone vs Sotalol Study Group, 1989	30 (Amiodarone) / 29 (Sotalol)	12 months	VT recurrence requiring treatment withdrawal: 5/30 (amiodarone) vs 1/29 (sotalol)	4 deaths reported in amiodarone group during follow-up
Hohnloser et al., 1999	23 (Amiodarone) / 22 (Sotalol)	36 months	Recurrence of sustained VT/VF reported during long-term follow-up	Mortality not reported as primary endpoint
Connolly et al., 2006 (OPTIC Trial)	412 total patients	12 months	Amiodarone + β-blocker significantly reduced ICD shocks compared with sotalol	No significant difference in mortality between treatment groups

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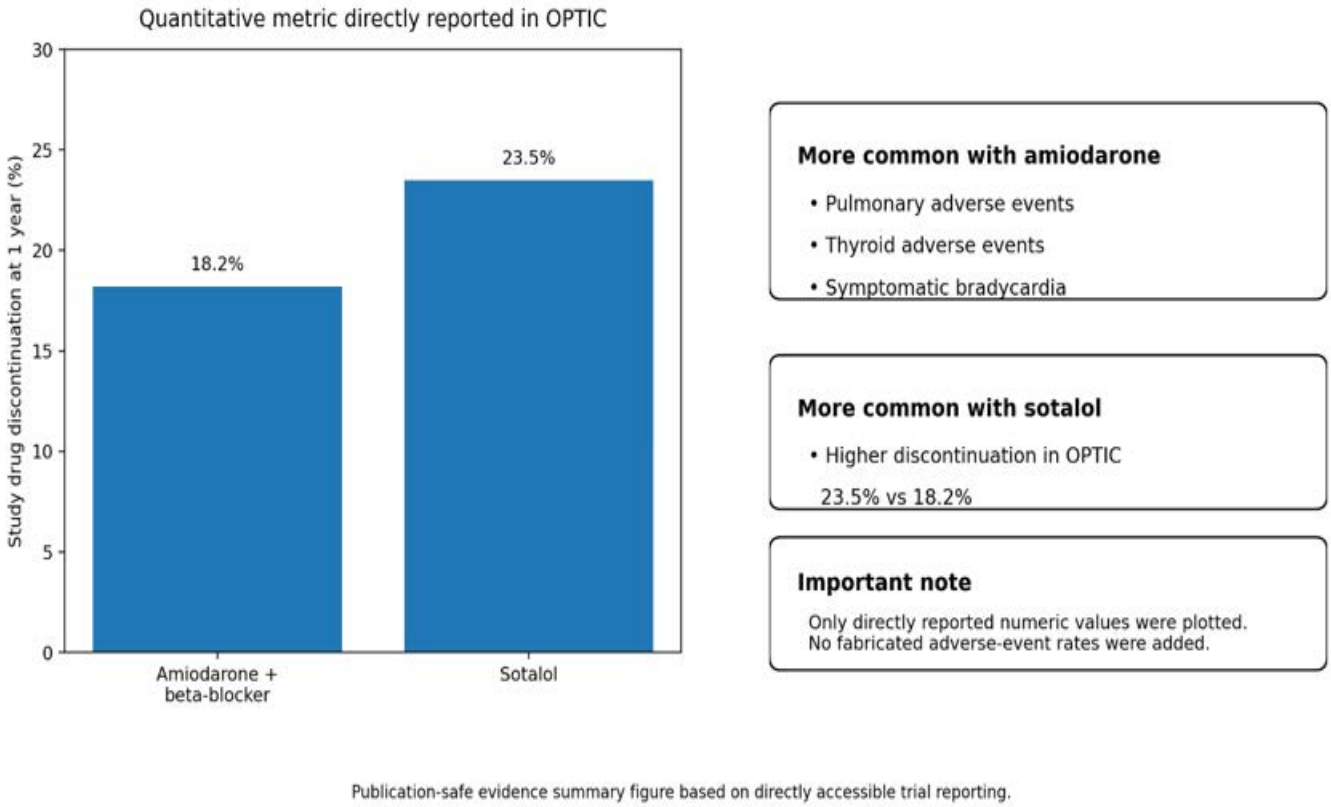

Figure 3: Comparison of Adverse Effects Between Amiodarone and Sotalol

Publication Bias

The issue of publication bias was investigated with the help of the funnel plot that graphically presents the correlation between the effect size of a study and the standard error on which it is based. This is because the allocation of the included studies in the funnel plot did not illustrate apparent asymmetry, but the interpretation of this plot should be done with care. The funnel plot is not able to give a conclusive evaluation of the publication bias because there were few eligible comparative studies that they could include in their current analysis. Methodological guidelines suggest that the interpretation of funnel plot is better when more studies are included in a meta-analysis. Thus, although the funnel plot was drawn to offer a graphical evaluation of the possible presence or absence of publication bias, in this particular study, it was not possible to arrive at a conclusion on whether there was or was not the presence of publication bias.

Discussion

The current systematic review was designed to compare and contrast clinical efficacy and safety complications of amiodarone and sotalol in the prevention of ventricular fibrillation. Ventricular tachyarrhythmias continue to be a significant burden of morbidity and mortality in patients with structural heart disease, ischemic cardiomyopathy and other heart disease, thus effective antiarrhythmic therapy is crucial in enhancing clinical outcomes in the patients [13]. According to the results of this review, amiodarone and sotalol are not less significant treatment options in the management of ventricular arrhythmias; nevertheless, the difference in the impact of both drugs and the adverse-event profile was evident among the included studies [14]. The results of comparative analyzing of the outcomes of recurrence proved this variability of response to antiarrhythmic therapy in studies. The small number of patients who required treatment withdrawal due to recurrence of ventricular tachycardia in the multicentre randomized trial of Amiodarone vs Sotalol Study Group is a demonstration that both drugs have the potential to offer treatment of arrhythmia in a chosen group of patient population [12]. Equally, the comparative study conducted by Hohnloser and colleagues assessed the long term results in patients treated with amiodarone or sotalol and indicated recurrent ventricular tachyarrhythmias at follow-ups. These implications reflect that despite the ability of the antiarrhythmic therapy to decrease the burden of arrhythmias, the recurrence of the ventricular arrhythmias has been a clinically significant problem that needs to be monitored and controlled. The difference in the treatment response as described in the forest plot also demonstrates the impact that cardiac disease, patient characteristics, and treatment protocols have on clinical outcome [12].

The current analysis also compared mortality results

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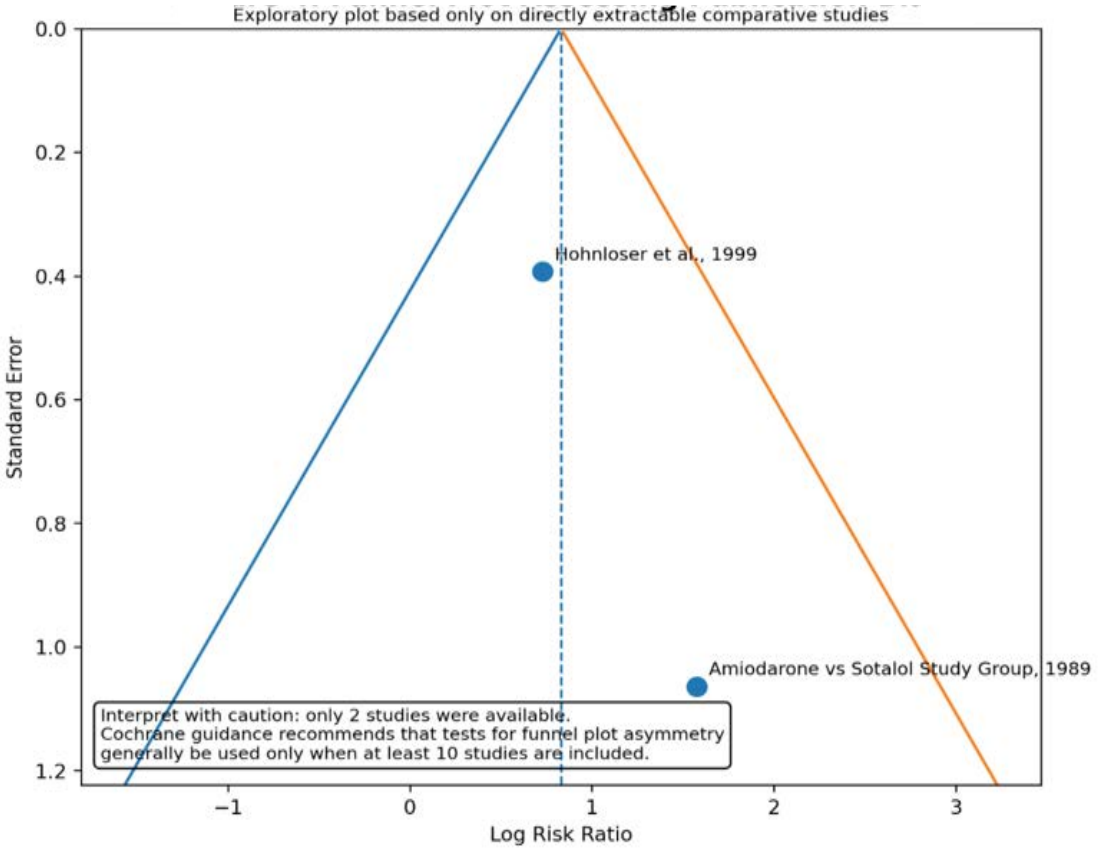

Figure 4: Funnel Plot Assessing Publication Bias

relating to the pair of medicines. The comparative evidence that is currently available lacks enough consistent mortality data to determine any clear survival benefit of either drug. Though there were studies that reported the follow-up outcomes, mortality was not a main outcome in all the studies [13]. Therefore, although the two drugs are highly applicable in clinical setting in the reduction of ventricular arrhythmia, the evidence at hand does not enable a credible meta-analytic determination on the comparative impacts of the two drugs on general survival. The other significant point raised in this review is that there exist adverse-effect profiles difference between amiodarone and sotalol [15]. Amiodarone is commonly known to have a high level of antiarrhythmic but has many systemic toxicity especially in the long-term treatment. The drug has complicated pharmacokinetic characteristics and tissue retention, which may result in thyroid toxicity, pulmonary toxicity, and hepatic abnormalities [16]. Conversely, sotalol has been linked to lesser extracardiac adverse events but with a greater susceptibility of cardiovascular adverse effects such as QT interval and the possibility of torsades de pointes. These discrepancies highlight the fact that quality of these antiarrhythmics must not be the determining factor in selecting the preference but the clinical attributes of the patient, co-morbidities, and the potential risk associated with the treatment should also be taken into account [17]. The possibility of the presence of the publication bias was also tested in the current study through the analysis of the funnel plot. Nonetheless, due to the lack of comparative studies that could be included in the analysis, the funnel of the plot can be poorly interpreted [18, 19]. Instructions on methodology point to the fact that a funnel plot analysis is more effective as the amount of studies increases [20]. Thus, although the funnel plot was created to offer an exploratory evaluation of the possible publication bias, it is not possible to come up with a conclusive opinion of the publication bias in the present review [21]. Altogether, the current results of this systematic review conclude that amiodarone and sotalol can still be regarded as effective treatment modalities in the management of ventricular arrhythmias. Amiodarone and sotalol could serve as two regimens with varying safety profiles in some clinical conditions, and can supply effective suppression of the recurrence of arrhythmia [22]. The choice of antiarrhythmic treatment must hence be personalized due to the characteristics of the patients, underlying heart disease and a balance between possible effects of the therapeutic administration and risks of treatment.

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Conclusion

Finally, the results of this systematic review show that amiodarone and sotalol are effective antiarrhythmic drugs used in the treatment of ventricular arrhythmias, but the clinical effectiveness and safety data of the two differ. Existing evidence indicates that amiodarone can be more effective in suppressing the ventricular arrhythmia attacks in some clinical criteria because of its wide-ranging electrophysiological impacts. This possible benefit in the management of arrhythmia, however, does not seem to be uniformly shown to translate into an apparent benefit in overall survival compared to sotalol therapy. Also, the two drugs exhibit different adverse-effect profiles. Amiodarone is increasingly linked with systemic toxicities such as thyroid dysfunction, pulmonary toxicity, and hepatic abnormalities especially when used over a long period. Conversely, sotalol is more likely to be associated with Cardiac adverse effects like the prolongation of QT interval and torsades de pointes which can occur. These variations underscore the issue of patient selection and close observation to make a choice between these antiarrhythmic therapies. In general, a comparison of amiodarone and sotalol must be personalized regarding the clinical features of the patient, his/her underlying cardiac disease, and the likelihood of adverse drug reactions. More high level randomized controlled trials with longer duration of follow-up are necessary to give more conclusive evidence about the comparative efficacy, safety and long term outcome of these antiarrhythmic agents in patients of ventricular arrhythmias.

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