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The use of wearable cardioverter-defibrillators in Europe: results of the European Heart Rhythm Association survey

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The aim of this European Heart Rhythm Association (EHRA) survey was to collect data on the use of wearable cardioverter-defibrillators (WCDs) among members of the EHRA electrophysiology research network. Of the 50 responding centres, 23 (47%) reported WCD use. Devices were fully reimbursed in 17 (43.6%) of 39 respondents, and partially reimbursed in 3 centres (7.7%). Eleven out of 20 centres (55%) reported acceptable patients' compliance (WCD worn for >90% of time). The most common indications for WCD (8 out of 10 centres; 80%) were covering the period until re-implantation of ICD explanted due to infection, in patients with left ventricular impairment due to myocarditis or recent myocardial infarction and those awaiting heart transplantation. Patient life expectancy of <12 months and poor compliance were the most commonly reported contraindications for WCD (24 of 46 centres, 52.2%). The major problems encountered by physicians managing patients with WCD were costs (8 of 18 centres, 44.4%), non-compliance, and incorrect use of WCD. Four of 17 centres (23.5%) reported inappropriate WCD activations in <5% of patients. The first shock success rate in terminating ventricular arrhythmias was 95–100% in 6 of 15 centres (40%), 85–95% in 4 (26.7%), 75–85% in 2 (13.3%), and <75% in 3 centres (20%). The survey has shown that the use of WCD in Europe is still restricted and depends on reimbursement. Patients' compliance remains low. Heterogeneity of indications for WCD among centres underscores the need for further research and a better definition of indications for WCD in specific patient groups.

Keywords Wearable cardioverter-defibrillator • Implantable cardioverter-defibrillator • Sudden cardiac death • Ventricular arrhythmias • Prevention • Heart failure • EHRA survey • EP wire

Introduction

Implantable cardioverter-defibrillators (ICDs) have proved effective in primary and secondary prevention of sudden cardiac death (SCD).[1,2] However, a significant proportion of patients presents with contraindications to ICD or does not meet the criteria for ICD implantation, as defined by current guidelines.[3] Nonetheless, patients with reversible cardiac impairment, such as acute myocarditis, or patients shortly after myocardial damage from other causes, or those with suspected primary electrical heart disease under diagnostic evaluation may be, at least temporarily, at a high risk of SCD. Furthermore, patients on the waiting lists for more advanced therapies may have temporarily increased risk of SCD.

The wearable cardioverter-defibrillator (WCD)—an external device worn by a patient on shoulder straps and equipped with electrodes for sensing/defibrillation along with a portable, rechargeable battery—may be considered an attractive temporary alternative to ICD. Despite the lack of randomized data, a growing body of evidence from non-randomized studies and registries suggests high effectiveness and satisfactory safety profile of WCD.[3–5] Accordingly, the recent guidelines of the European Society of Cardiology (ESC) state that the use of WCD may be considered in selected groups of patients.[6] However, current clinical practice of WCD use in European countries remains largely unknown. The aim of this European Heart Rhythm Association (EHRA) survey was to gather data on WCD utilization in the European electrophysiology (EP) centres.

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Methods and results

Participating centres

This survey was based on a questionnaire sent via the internet to the EHRA EP research network centres. Of 50 responding centres, 47 (94%) were university hospitals, 2 (4%) were private hospitals, and 1 centre (2%) was another hospital type. In 7 centres (14%), no cardiac implantable electronic devices were implanted or replaced last year, 8 centres (16%) implanted 300–399 devices, and 19 centres (38%) implanted >400 devices. At least one catheter ablation was performed within the last calendar year in 46 centres (92%), including 6 centres (12%) with 300–399 ablations and 15 (30%) with >400 ablations performed. Most centres ($n = 47$; 94%) had cardiac surgery available on-site.

Utilization and reimbursement of wearable cardioverter-defibrillators

The use of WCD in clinical practice was reported by 23 (47.0%) of 49 centres which responded to this question. Of these, 11 centres (48.0%) equipped <10 patients with WCD during the last 12 months, 5 centres (22.0%) used WCD in 10–29 patients, 5 centres used WCD in 30–49 patients, and 1 centre (4.0%) used WCD in 50–100 patients.

Only 15 of 36 responding centres (42.0%) reported the full reimbursement for WCD in their country, while in 3 centres the reimbursement was partial. Of the latter, patients shared the costs of WCD in two centres, and in one centre the hospital contributed to the cost. No reimbursement was reported by 18 centres (50.0%). According to the WCD reimbursement policy, 10 (66.7%) of 15 centres which declared the availability of full reimbursement did use the device, all 3 centres with partial reimbursement reported that they used WCD in their patients, and only 5 (27.8%) of 18 centres without reimbursement used WCD in their patients.

Indications and contraindications for wearable cardioverter-defibrillators

Half the centres (11 of 22 centres which responded to this question) used WCD for in- and outpatients, 8 (36.4%) used the device for outpatients only, and 3 centres (13.6%) for inpatients only. The most common indication for WCD [reported by 8 (80.0%) of 10 centres which answered this question] was to cover the period until device re-implantation in patients with ICD explantation due to infection. The second most common indication was acute myocarditis with depressed left ventricular (LV) ejection fraction (7 centres; 70%). Impaired LV function within the early post-infarction phase and awaiting heart transplantation were the indications reported by 4 centres each (40.0%), and depressed LV ejection fraction shortly after myocardial revascularisation or recently diagnosed non-ischaemic cardiomyopathy was the criteria used less commonly to qualify patients for WCD (3 centres, 30% each; *Figure 1*, upper panel).

Patient life expectancy of <12 months and poor compliance [24 centres each (52.2%) of 46 responding centres] were the most commonly reported reasons which would make WCD use less probable, even in patients otherwise suitable for this therapy. Less frequent contraindications were age >75 years (12 centres, 26.1%), atrial fibrillation (8 centres, 17.4%), implanted pacemaker/cardiac resynchronization device, or severe renal failure (6 centres each, 13.0%). Eleven centres (23.9%) would not use any single criterion to disqualify patient from WCD (*Figure 1*, lower panel).

Duration of device use and patients' compliance

In most of the responding centres (12 of 19, 63.1%), the scheduled duration of WCD use was 1 month, in 6 centres (31.6%) WCDs were scheduled for 3 months, and in 1 centre (5.3%) for 15 days. Eleven of 20 responding centres (55.0%) reported that the actual time their patients did wear WCD exceeded 90% of the scheduled time, 7 centres (35.0%) observed patients' compliance for 50–90% of time, 1 centre for 10–50% of time, and 1 centre (5.0%) reported patients' compliance for <5% of the scheduled time.

Concerns associated with device use

From the physician's point of view, the cost-related issues were the major obstacles for the use of WCD. In 8 (44.4%) of 18 responding centres, costs represented a very important issue when considering WCD use, and in 7 centres (38.9%), cost issues were moderately important (*Figure 2*, upper panel). The second most important issue was the concern about patients' non-compliance, which was very important in 7 centres (38.9%), and the third important concern was potentially incorrect use of WCD by the patient (incorrect placing of electrodes or use of response button, etc.), reported as very important by 7 of 19 responding centres (36.8%).

According to the physicians' perception, patients' major concern was the anxiety or fear of receiving the shock from the device. Seven of 15 responding centres (46.7%) declared this issue very important for their patients. The second most significant problem was discomfort and inconvenience associated with WCD use (reported as very important by 7 of 18 centres, 38.9%), and the third was the sleep disturbance resulting, for example, from inappropriate alerts emitted at night by WCD (6 centres, 35.3%; *Figure 2*, lower panel).

Inappropriate shocks and effectiveness of wearable cardioverter-defibrillators

Less than one-fourth of the responding centres (4 of 17 centres, 23.5%) reported inappropriate interventions delivered by WCD, occurring in <5% of their WCD patients. The main reason of inappropriate interventions was a misdetected pacing artefact from an implanted cardiac device and double counting of the T wave (each reported as a very frequent cause by 5 of 13 centres, 38.5%). Less frequent causes were supraventricular tachycardia and atrial fibrillation or flutter (very frequent in 3 centres, 23.1%), and non-sustained ventricular tachycardia (2 of 12 centres, 16.7%; *Figure 3*).

The success rate of the first shock in terminating ventricular arrhythmia was 95–100% in 6 (40.0%) of 15 responding centres, 85–95% in 4 (26.7%), 75–85% in 2 (13.3%), and <75% in 3 (20.0%) of the centres.

Discussion

This EP Wire provides an insight into contemporary European practice regarding the use of WCD, mostly in the university hospitals. A relatively low response rate (50 centres) and incomplete responses are the limitations.

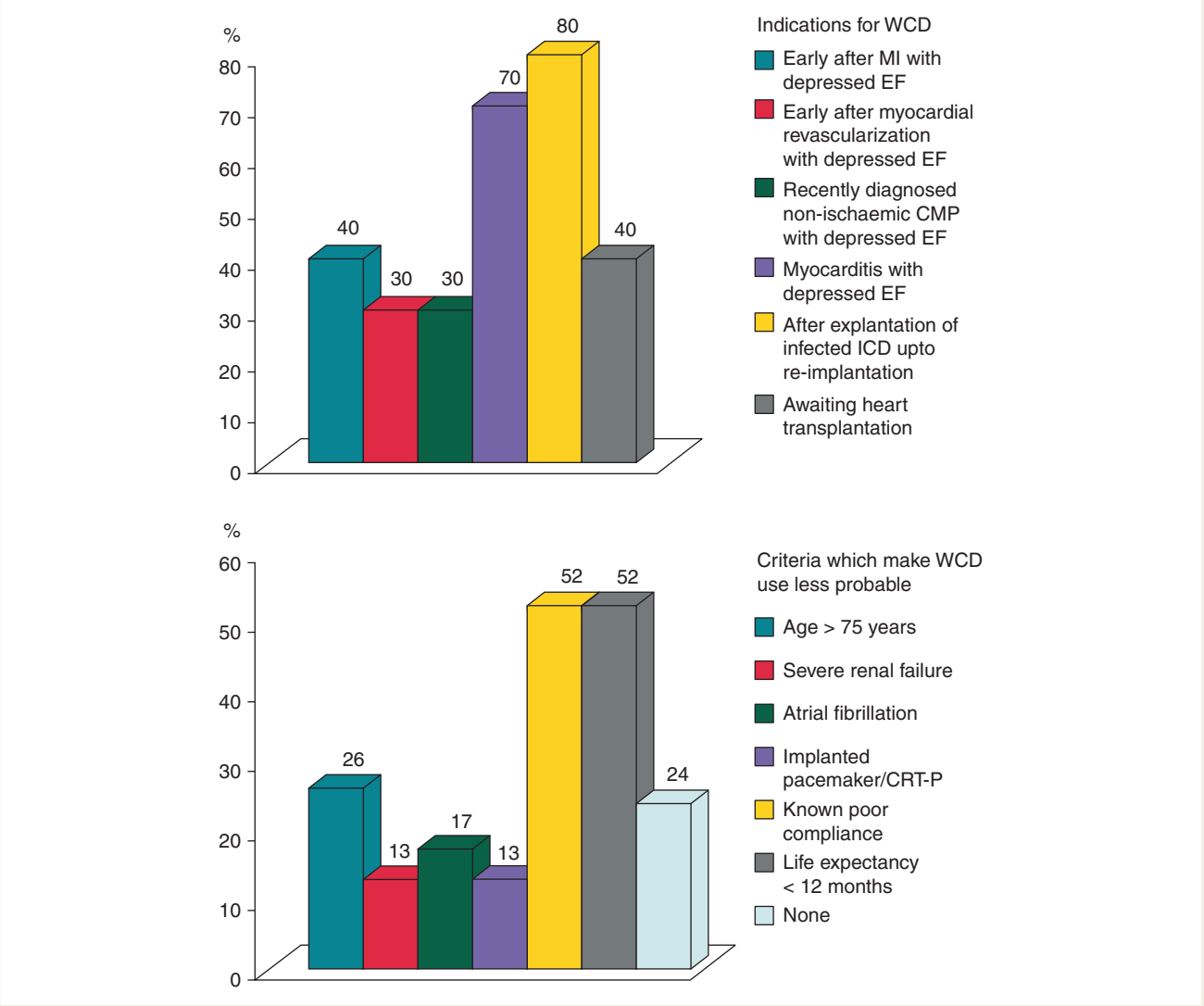

Figure 1 Indications (upper panel) and contraindications (lower panel) for WCDs. MI, myocardial infarction; EF, ejection fraction of the left ventricle; CMP, cardiomyopathy; ICD, implantable cardioverter-defibrillator; CRT-P, cardiac resynchronization therapy-pacing.

The main findings of this survey are as follows: (i) a moderate use of WCD in clinical practice in Europe (less than half the centres used WCD); (ii) a highly variable reimbursement policy across the European centres (WCD use is fully reimbursed only in a minority of European countries, and there was a close relationship between repayment and WCD use); (iii) a low patients' compliance with the WCD (approximately half the centres reported insufficient adherence of their patients to instructions on how to use WCD); (iv) a variation in the indications for WCD among the centres, whereas anticipated patients' non-compliance and short life expectancy were universally perceived as disqualifying conditions; and (v) the efficacy of WCD, which was seemingly high, but inappropriate interventions were frequently reported.

Wearable defibrillators use and reimbursement

The first report on successful WCD use was published almost 20 years ago,[7] but its clinical use is still not widespread in Europe. In the present survey, less than half of the centres reported WCD use in clinical practice, and 48% of these centres used WCD in <10 patients during the last year. There are several possible reasons for such a low availability of the device in Europe, with limited expenditure on healthcare being probably among the most important ones. In our survey, less than half of the centres reported full reimbursement of WCD and half of the centres reported no reimbursement. The costs were the main concern associated with WCD use, and there was a close association between the level of funding and availability of this therapy. Similar relationship between the level of expenditures on healthcare and access to cardiac implantable electronic devices or EP procedures in Europe has been shown in the recently published report from the EHRA.[8]

Another source of constrained WCD use may be represented by the limited data on safety and efficacy of this therapy. Although the results of several observational studies on WCD are very promising,[3,4] data from the randomized, controlled trials are lacking. In addition, WCD use in selected patients has received a Class IIb

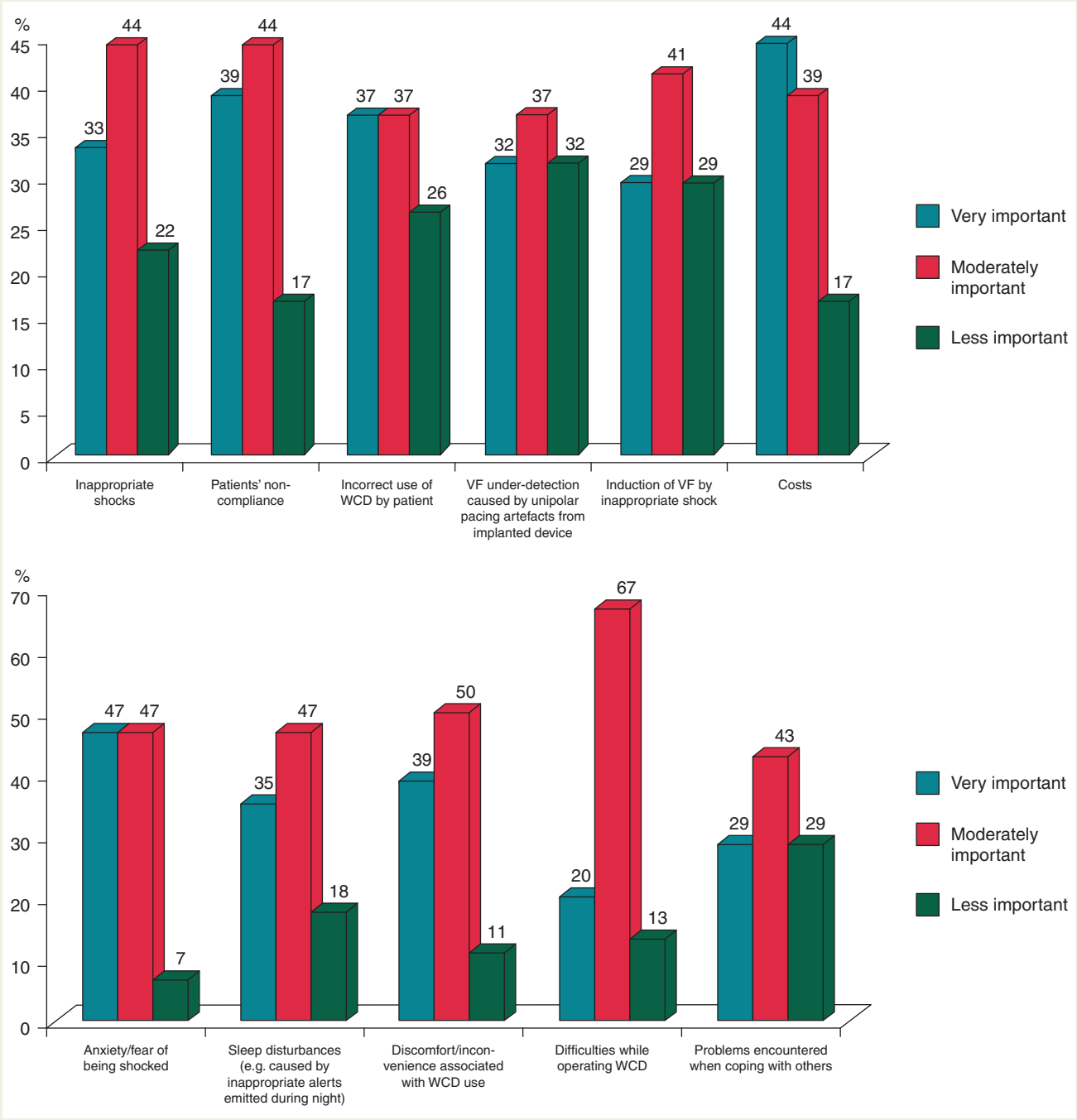

Figure 2 Major concerns associated with the use of WCDs from physicians' (upper panel) and patients' (lower panel) perspectives. WCD, wearable cardioverter-defibrillator; VF, ventricular fibrillation.

recommendation in the recent guidelines of the European Cardiac Society.[6]

Patients' compliance

Patients' compliance was one of the major concerns when considering WCD therapy. The recommended time WCD should be in use is 24 h per day, with the exception of short periods for a shower or bath. However, in our survey, only 55% of the centres reported acceptable patients' compliance rate (i.e. WCD worn for >90% of the scheduled time). Similarly, in the registry by Chung *et al.*,[5] only half of the patients wore the defibrillator continuously. Importantly, poor compliance or inappropriate use of WCD may have catastrophic consequences. All 6 cases of SCD in the WEARIT/BIROAD trial occurred in patients either not wearing WCD at all (5 cases) or incorrectly using the device (1 case).[4] Because WCD use may be monitored online, detection of incorrect use of the device is possible and should enforce a prompt feedback and motivation of a non-compliant patient. Alternatively, other forms of monitoring or therapy can be discussed (home monitoring with portable defibrillator, early ICD implantation, etc.)

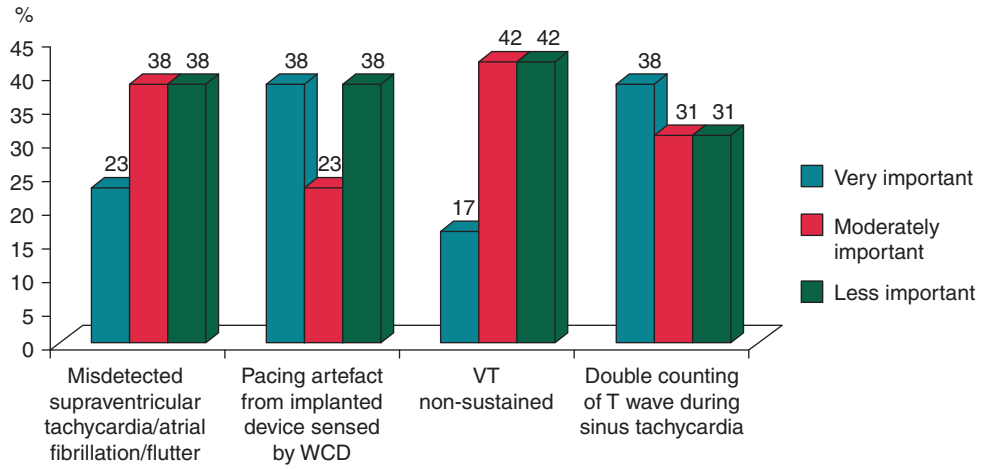

Figure 3 Causes of inappropriate therapies. WCD, wearable cardioverter-defibrillator; VT, ventricular tachycardia.

Indications and contraindications

No formal consensus on the indications for WCD is currently available. Current ESC guidelines suggest that patients on the waiting list for heart transplant or for ICD implantation, those with peripartum cardiomyopathy, active myocarditis, and with severe early post-infarction arrhythmias should be potential candidates for wearable defibrillator.[6] Accordingly, centres that responded to our survey were guided by a mixture of criteria while considering WCD use, with significant variability seen between various centres. The most common indication for WCD was to cover the period until device re-implantation in patients with ICD explanted due to infection. On the other hand, patient life expectancy of <12 months and poor compliance were the most commonly reported contraindications for WCD.

This heterogeneity in indications among the centres and the tendency to exclude specific vulnerable patient groups reflect the lack of information on the role that WCD may play in particular subpopulations and underscore the urgent need of further studies.

Effectiveness of antiarrhythmic therapy and inappropriate therapies

The effectiveness of WCD in terminating malignant arrhythmias was high in our survey. These results are in line with data published previously and support the high efficacy of this form of therapy.[3–5] Considering WCD safety, less than one quarter of the centres reported inappropriate therapies in their patients; however, the incidence was relatively low ($<5\%$ of all patients).

Conclusion

Our survey has demonstrated that the use of WCD in Europe is still restricted and remains highly dependent on reimbursement. Compliance of WCD patients remains low and may lead to suboptimal therapeutic effects in a significant proportion of treated subjects. The heterogeneity of WCD indications among the European centres underscores the need for further research, to better define the impact of WCD on specific patient groups.

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