A NEW INEXPENSIVE CARDIAC PACING SYSTEM

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INTRODUCTION

Permanent electrical pacing of the heart is firmly established as the treatment of choice in certain cardiac conditions, principally symptomatic complete heart block. However, full utilisation of this type of therapy has been impossible in the developing countries because of the very high cost of the permanent pacemaker.

The investigations described in this communication have been directed towards designing a less expensive permanent pacing system, suitable for use in a developing country. A preliminary report of the clinical use of this pacemaker is given.

CHOICE OF SYSTEM

There are, basically, three methods for permanent cardiac pacing. The vast majority of permanent pacemakers are of the totally implanted type while a much smaller number are of the induction type where only a coil and electrodes are implanted but the power source and impulse forming circuit are carried outside the body. The third type of pacing involves bringing leads out through the skin and has been largely discarded because of the hazard of sepsis.

The totally implanted pacemaker is costly and must be totally replaced every two to three years. The main hope of reducing the per year cost of this type of pacing lies in the development of longer lasting power sources, such as the nuclear battery, as most replacements are now carried out for battery depletion. It is clear, however, that the initial cost of this type of pacemaker will remain high. The recurring cost might be reduced, however, if the pacemaker were designed in such a way that the battery pack could be replaced separately. Alternatively, it should be possible to design the unit in such a way that, after recovery from the patient, the depleted batteries could be removed and replaced, thus producing a cheap 'reconditioned' unit. However, in choosing a design suitable for production in India, the totally implanted type was rejected as it requires many components and techniques not available in India. In addition, follow-up would be difficult, posing a considerable hazard to the patient if the pacemaker proved to be unreliable.

The method using the induction coil principle seemed the most promising as the number of implanted electronic components can be kept to a minimum and the impulse forming circuit and power source, placed externally, are readily available for servicing and can be made entirely of indigenous components at low cost.

A major disadvantage in any induction system previously described has been the necessity of wearing the primary coil applied over the secondary coil and held in place with adhesive tape. This is not practicable in warm sub-tropical areas where the adhesive would soon become loosened by perspiration. However, Andren et al[1] described a 'skin-tunnel transformer' where the implanted coil is brought out in a tube of skin and the induction element is a ring of ferrite material applied round the tube. Not only would this allow induction of an impulse efficiently but there would be no danger of displacement of the primary coil. It was decided to build an external radio-frequency induction pacing system using a skin-tunnel transformer, therefore.

MATERIALS AND METHODS

A schematic diagram of the final system is given in Fig. 1. The external generator produces an impulse in the form of a one milli-second train of 300 KHz radiofrequency current which is applied to an external wire, looped once round the toroid*. This induces a current in the implanted wire, in the skin loop. This current is half-wave rectified and applied to the heart.

The implanted component is in two parts. The endocardial pacing lead has a 304 medical grade stainless steel tip with silicone-rubber covered Elgiloy** spring-coiled wire as the lead (Fig. 2). The wire for the skin tube and the diode plus indifferent electrode is manufactured as a single unit, the wire being exactly similar to the endocardial lead. The four diodes (Fig. 3), used for redundancy, are potted in epoxy resin inside a 304 or 316 stainless steel capsule, which also acts as the indifferent electrode (Fig. 4).

The power source is a 9-volt transistor radio battery.***

(a) In Vitro Tests

The total system was built and subjected to bench testing with the ends of the wire connected across a 470 ohms resistance. Various corrosion studies (to be reported elsewhere) were carried out in vitro to assess the corrosion danger at the indifferent electrode.

(b) In Vivo Tests

The system was implanted in a sheep. The skin tube was formed in the neck and, once the wound was healed, the toroid, previously scored and broken in half, was reassembled round the tube. The loop from the external generator was passed through the toroid and the generator slung from a collar on the neck (Fig. 5). An E.C.G. was recorded at the time of applying the system and at roughly weekly intervals. Note was kept of the battery voltage and the pacing threshold. After 3½ months, while pacing was continuing, the experiment was ended and an autopsy performed.

(c) Clinical Trial

Two patients who could not afford the conventional type of pacemaker were offered the new system. In patient A, the endocardial lead was used, via the saphenous vein (Sloman et al[2]). In the other, myocardial leads were preferred because a temporary endocardial lead had displaced on three occasions. In both, the skin tunnel was formed in the inguinal fossa (for cosmetic reasons. The external generator consisted of two pacing circuits with a switch between them (Fig. 6) worn in a leather case on a belt (Fig. 7).

RESULTS

(a) In Vitro Tests

The unit's performance was entirely satisfactory on bench testing. There was no undue corrosion of the capsule.

(b) In Vivo Tests

Satisfactory pacing of the sheep's heart was obtained as soon as the pacemaker was applied and was continuing when the experiment was ended (Fig. 8).

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** Elgiloy Co., Dundee Ave., Elgin, Ill. U.S.A.

*** Eveready Co., India.

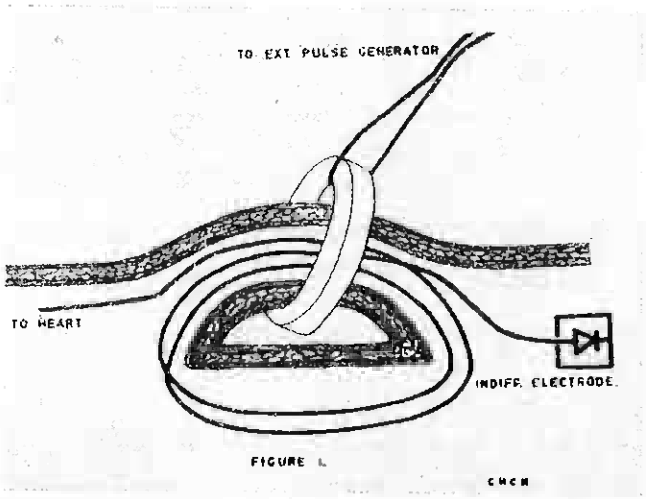

Fig. 1. Schematic Diagram to illustrate the principle of the 'skin-tunnel transformer'.

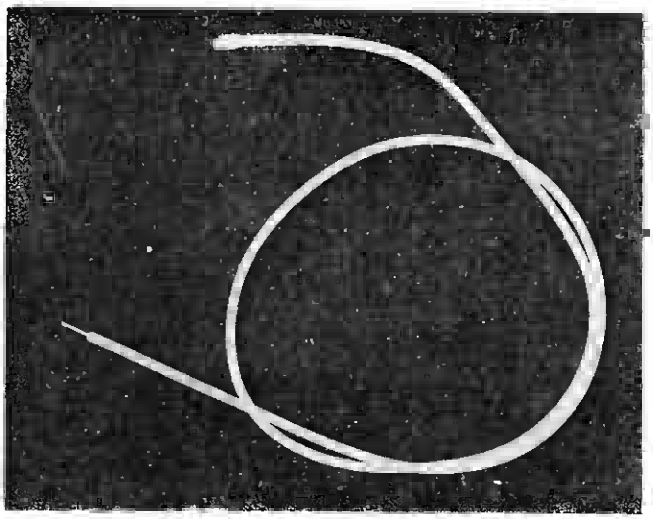

Fig. 2. Endocardial Pacing Lead.

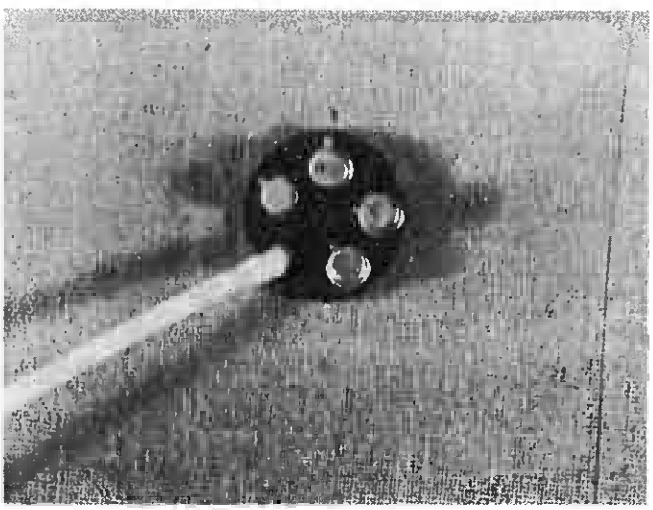

Fig. 3. The only implanted electronic components—4 diodes (for redundancy).

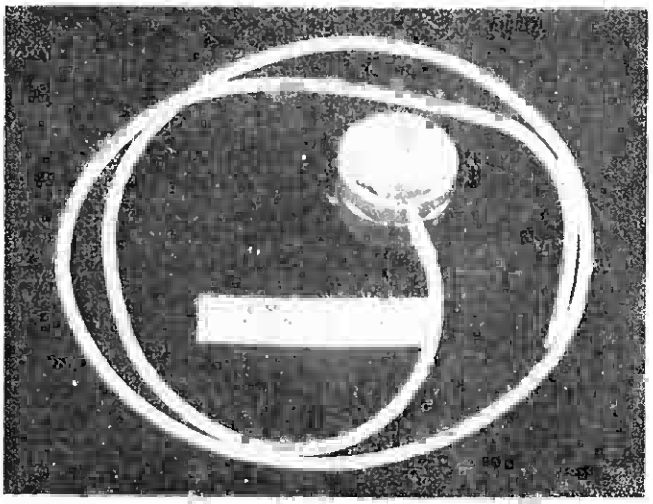

Fig. 4. Indifferent electrode and wire for skin tunnel.

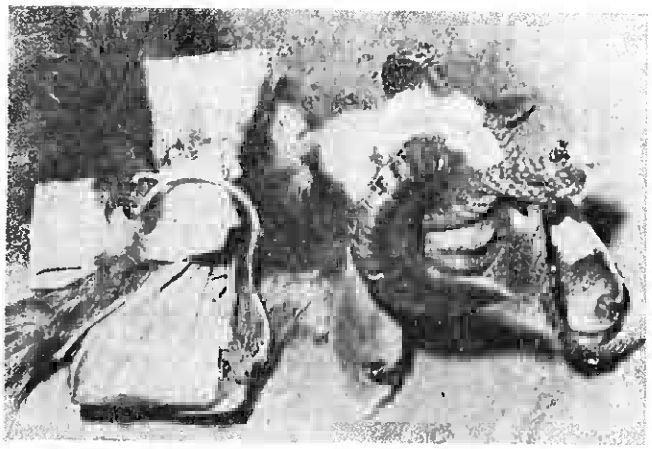

Fig. 5. System implanted in a sheep.

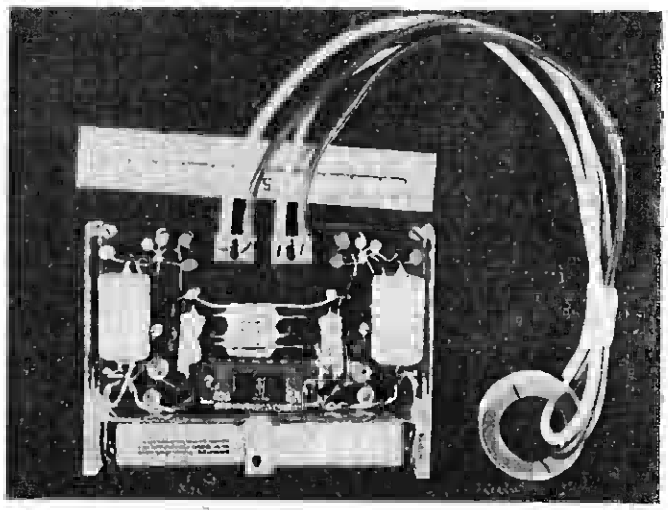

Fig. 6. The External Generator.

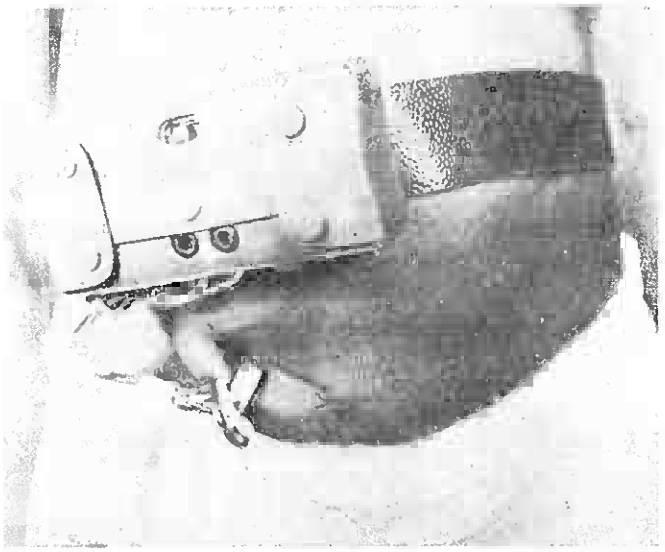

Fig. 7. System as worn by patient (earlier model generator).

Fig. 10. Sheep heart opened to show endocardial lead at apex of R.V.

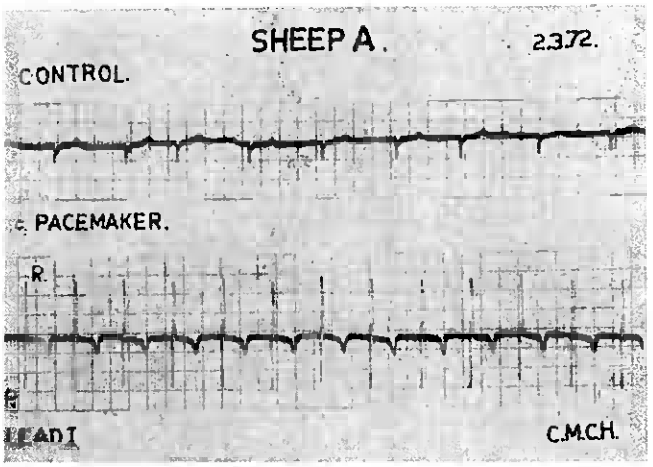

Fig. 8. Sheep E.C.G. before and during pacing.

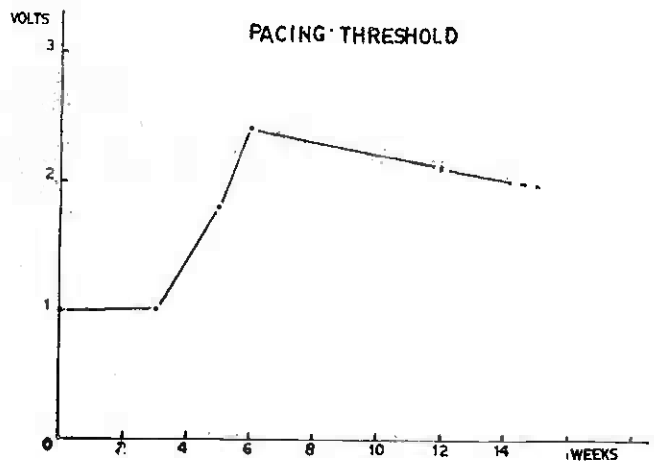

Fig. 9. Pacing Threshold in the sheep.

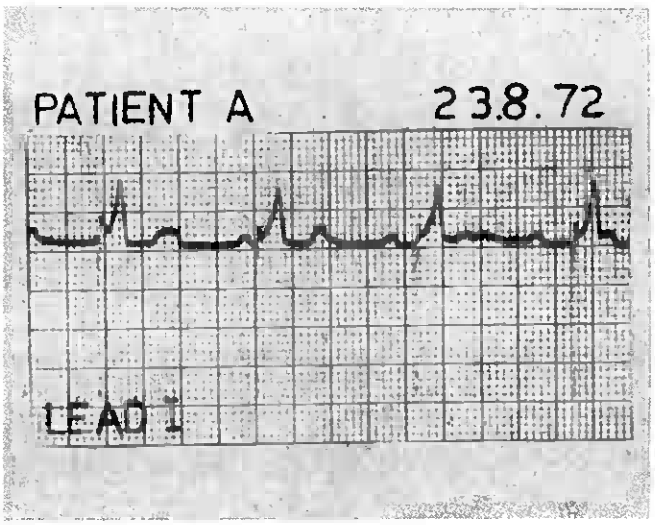

Fig. 11. ECG of patient A showing satisfactory pacing.

The batteries lasted on average 21.5 days with no battery lasting less than 16 days. After showing an initial sharp rise, the pacing threshold stabilised at about 2.1 volts. (Fig. 9)

At autopsy, all the components of the system were intact. The electrode tip was firmly adherent to the R.V endocardium at the apex (Fig. 10). The skin tube was lined on the inside with glistening membrane, such as invariably forms round silicone rubber implants. The capsule did not show any areas of undue corrosion.

(c) Clinical Trial

At the time of writing, patient A has had his pacemaker for 6 weeks. Satisfactory pacing was established immediately (Fig. 11). At five weeks, one pacemaking circuit failed. This caused no upset to the patient as the switch was moved to the other circuit, which was working normally. Subsequent examination of the pacemaker revealed a faulty soldered joint and repair of this restored its function.

The other patient has shown satisfactory pacing in the few days since application of the pacemaker.

DISCUSSION

The most important attribute of any pacing system is its safety or reliability. This is achieved, in the totally implantable types by using extremely reliable electronic components and monitoring for premature battery exhaustion by careful follow-up. This approach is costly. An alternative approach, used here, is to have the electronics accessible and duplicated. Thus,. although the electronic components may be less reliable, it is extremely unlikely that two circuits will fail simultaneously. Later models will contain an alarm, increasing its safety. Thus, any fault in one circuit need not produce an emergency situation but can be dealt with 'at leisure' while the patient is maintained on the other circuit. Battery depletion is, of course, easily monitored and routine replacement of the inexpensive batteries can completely remove this potential cause of pacemaker failure. In certain situations, it might be desirous to change the amplitude or frequency of the pacing stimulus. This is readily achieved using the induction type of pacemaker.

Next to safety, our major concern has been to produce an inexpensive pacemaker. This has been achieved by using simple circuits without complicated technology and 95% indigenous components. Thus, the pacemaker costs less than one third the cost of any other pacemaker at present available. Because the pacemaker has been built in such a way that it can be easily repaired, if necessary, recurring costs should be small.

If the simple implanted component proves to be reliable and durable, many fewer reoperations should be necessary, when comparing with the totally implanted type where repeated reoperation for battery exhaustion is necessary.

A unique advantage of the present system of induction pacing over any other system of induction pacing previously described, is that, by using the skin tunnel, the problems of maintaining good approximation of the primary and secondary coils and of skin hygiene under the primary coil are effectively overcome.

However, this type of pacing shares with other types of induction pacing the disadvantage that non-competitive pacing is not practicable. Thus, in cases of intermittent heart block, competition from the patient's own pacemaker may occur and this may not be entirely suppressed by pacing at a faster rate or using drugs.

Another disadvantage is that the surgery at original implantation is a little more complicated, involving some plastic surgery. This should not be beyond the average surgeon, however!

Pilcher and Heely[3] in an appraisal of a British induction pacemaker, concluded that the main disadvantage of this type of pacing was psychological and that, in retrospect, 12.5% of their patients had been unable to adjust psychologically to the constant external evidence of their dependence on a machine to maintain cardiac function. However, although most would agree, by and large, with this conclusion, when the alternative for our patients is not a totally implanted type but the generally unsatisfactory drug treatment, with the possibility of developing symptoms at any time, they may find the external generator a reassurance rather than the opposite.

SUMMARY

A new inexpensive permanent pacing system, using an induction device, has been designed and tested in animal experiments. The system uses 95% indigenous components and 9-volt transistor radio batteries. A skin tunnel transformer forms the induction element, thus overcoming problems associated with maintaining good position of the primary coil and skin hygiene, found in other systems. For safety, the external generator is duplicated and the simple implanted component has built-in redundancy. Preliminary results of a clinical trial are encouraging.

ACKNOWLEDGMENTS

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