ULTRASONIC THERAPY OF MÉNIÈRE'S DISEASE

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During the past twenty-five years notable advances have been made in the knowledge of the physiology, pathology, and biochemistry of the inner ear. With each advance more light has been thrown on the complex problems of Ménière's disease, but there are many cases of this disorder which still fail to respond to conservative treatment. Although there is no direct danger to life, except by accident, or to health from the disease itself, the effects are most damaging psychologically and interfere so much with locomotion as to render the patient's life almost intolerable. These patients are ready to submit to almost any treatment, even to the infliction of total deafness, to rid themselves of the attacks.

Unilateral total destruction of the whole inner-ear function provides dramatic relief for these patients.

For many years otologists have sought a weapon that could destroy the vestibular apparatus while sparing the cochlea. The objectives in treatment are to abolish vertigo, to abolish tinnitus, and to improve hearing. Until 1952 (Krejci, 1952) the nearest approach to this ideal was the section of the vestibular branch of the eighth nerve in the posterior cranial fossa or administration of doses of streptomycin large enough to cause neuronitis of both vestibular nerves. In 1953 Arslan (1955) described the first practical method of selective destruction of the vestibular end-organ with ultrasonic vibrations. By a most ingenious design of apparatus the focused beam of ultrasonic vibration was applied direct to the labyrinth. He has used this apparatus in over 600 cases (Arslan, 1958).

The principles of this method depend upon the generation of ultrasonic vibrations by the passage of an alternating electric current of a million cycles per second through a quartz crystal. Ultrasonic vibrations of this same frequency are generated in the crystal and focused in a metal cone, and transmitted by a metal rod to the labyrinth. The escape of lateral vibrations is prevented by a metal sheath around the rod with an air-gap between it and the rod. Since the conduction of ultrasonic vibrations of this frequency and power from metal to air is negligible the danger of lateral vibrations damaging normal structures in the vicinity of the labyrinth is thereby eliminated. For this same reason it is necessary to apply the treatment rod direct to the labyrinth itself.

For the past three years we have been engaged upon the investigation of the physical properties of ultrasonic vibrations of these frequencies generated in this way and applied to the temporal bone with its complex

structure and containing bony, fluid, nervous, and neuroepithelial structures. Fortunately bone, soft tissues, blood-vessels, and dura mater are relatively resistant to the damaging effects of ultrasonics, but myelinated nerves, nerve cells, and neuroepithelium appear to be very sensitive. Bone is a poor conductor of ultrasonics, while liquids are excellent conductors (Angell James *et al.*, 1960).

Objective of Treatment

Our objective in the treatment of Ménière's disease is the destruction of the neuroepithelium of the cristae of the semicircular canals and the maculi of the utricle and saccule.

There are three major hazards which we must avoid: firstly, the facial nerve; secondly, the cochlea; and, thirdly, the temporal lobe and cerebellum. Of these three hazards the facial nerve causes the greatest anxiety. Many articles have been published in which the hazard to the facial nerve has been stressed (Dubs, 1957; Lumsden, 1958; Altmann and Waltner, 1959), and because of the frequency of facial paralysis many surgeons have abandoned the method. We are convinced that it is heat which constitutes the greatest danger of facial-nerve damage. The other danger is that of direct irradiation of the nerve by the ultrasonic beam.

Much heat is generated in the crystal and treatment head when the apparatus is working. If the temperature rises too high it can split the crystal. An efficient pump-operated hydrostatic cooling system has now been incorporated in the apparatus which cools the treatment head, but in spite of it the treatment rod becomes very hot while the apparatus is warming up.

The most important hazard is the development of too high a temperature in the bone. In Arslan's original description of ultrasonic destruction of the labyrinth it was advised that the treatment rod should be applied direct to the prominence of bone over the external semicircular canal, and that the field should be kept completely dry throughout the application. Before we used this method we measured the heat generated using this technique, and to our dismay discovered that the temperature beneath the bone to which the treatment rod was applied could rise to no less than 90° C. in a matter of a few seconds after the application. We therefore modified the method and introduced liquid coupling and continuous irrigation, with the temperature monitored all the time by a very small thermo-couple which is inserted in a depression in the bone behind the treatment rod.

The objects of this technique are threefold. (1) By using liquid coupling between the end of the rod and the bone the conduction of the ultrasonics into the labyrinth is much more efficient. If the end of the treatment rod, which is flat, could be applied perfectly to a flattened bony surface and held exactly in contact this liquid coupling would not be necessary. But as it is physically impossible to achieve this perfect contact the liquid coupling is the next best alternative. (2) By using continuous irrigation we are able to control the temperature of the bone and avoid damage to the facial nerve. (3) The control of temperature changes avoids the caloric labyrinth reaction which might otherwise occur and interfere with the important nystagmic responses from which the effect of the ultrasonic vibrations on the labyrinth can be gauged.

The irrigating apparatus we employ consists of two vessels, the one containing water at 100° F. (37.8° C.) and the other cold water. These are joined by wide-bore rubber tubes to the irrigating tube of a Shambaugh irrigating apparatus. With the thermo-couple in place on the bone beside the treatment rod for monitoring it is possible for an assistant to alter the temperature of the irrigating fluid to maintain the temperature around the rod at 37° C. A deep bath of saline is maintained by raising the sucker tube of the apparatus to the level of the surface of the mastoid bone. This bath is of great importance, because if the patient has an acellular mastoid there is very little space left between the dura and the incus to allow the treatment rod to be applied firmly to the lateral semicircular canal. The space around will contain only a very little fluid at any one time. The importance of this was demonstrated in the one patient in our series in whom we have damaged the facial nerve. This case was so instructive that it is recorded below. Apart from this one accident we have never observed the slightest interference with the facial nerve in any one of our patients, even when the facial nerve has been bared in the course of the operation. It was as a result of this accident that we introduced the method of thermal control with thermo-couple monitoring.

There is only 1 mm. between the facial nerve and the lateral semicircular canal. Therefore the ultrasonic beam emitted from the treatment rod must not spread out laterally. We found that it was necessary to use a special tuning monitor to assure this and to retune every five minutes during the treatment, and always when increasing or decreasing the power output. This assures the operator of a constant beam pattern, which we have shown by Schlieren photography to correspond closely to the width of the treatment rod. By meticulous care and watchfulness the dangers of irradiation of the facial nerve and brain can thus be avoided.

Points in Operative Technique

The operative technique we adopt was described in detail in a previous paper (Angell James *et al.*, 1960), but the most important points to observe are as follows.

The operation is performed under local anaesthesia and premedication with pethidine and promazine hydrochloride ("sparine"), in order to retain the patient's co-operation. We can then observe the direction of the nystagmus which gives the signal to indicate, first that irritation has begun, and then that the paralysis of the vestibular neuroepithelium has been achieved. The nystagmus and the movement of the

facial muscles must be continually observed throughout the whole proceeding. Under simple infiltration local anaesthesia the mastoid process is opened and the prominence of bone over the lateral semicircular canal freely exposed, together with the short process of the incus, after removal of sufficient bone to allow the treatment rod to reach the lateral semicircular canal. The surface of the lateral canal is burred down as flat as possible and at the most suitable angle to allow the treatment rod to be applied with as close a contact as can be obtained over a wide area. To assist in achieving this a "perspex" model of the treatment rod is used. By looking through the transparent rod the contact between labyrinthine bone and the end of the rod can be seen.

The burring is performed under the operating microscope, and is carried down to the point at which the lateral semicircular canal is clearly visible as a blue line. It is very important not to craze or crack through the bone over the canal. In our experience this has resulted in loss of cochlear function in the two cases in which this accident happened. This burring down to a low level has the further advantage that the ultrasonic beam-tip is lower down compared with the level of the facial nerve. A fault in aiming will probably pass the beam beneath rather than into the facial nerve in the fallopian canal. As soon as this preparation has been made the suction tube is drawn up, until it sucks only from the level of the surface of the mastoid process. The treatment head is tuned and the rod applied with the thermo-couple in place beside it. To begin with a power of 4 watts/sq.cm. is used, and this causes very little distress to the patient. Within a few seconds of the application the patient usually complains of vertigo and the irritative nystagmus is observed. The quick component of the nystagmus is towards the operated side. If the patient is too deeply sedated nystagmus may not be observable, but instead there is deviation of the eyes towards the opposite side.

After five minutes' application the treatment head is retuned and reapplied and the application continued until a paralytic nystagmus develops. This direction is towards the opposite side. After it has been present for at least five minutes we alter the aiming of the treatment head to try to pick out the superior and posterior canals. If no rotary or vertical nystagmus follows we then increase the power to 6 watts/sq.cm. and continue this for five minutes. In some patients even when cooling is holding the temperature at 37° C. there may be a sensation of pain at high intensities. We have never used more than 8 watts/sq.cm. and usually only 6 or 7 watts are tolerated. In the early stages, after paralytic nystagmus has begun, it is often reversed and becomes irritative again when the treatment is resumed after a few seconds' interval while the transducer is being retuned. We measure our final five minutes of 6 watts power from the last time when irritation was observed after a retuning interval. The average time taken is approximately 21 minutes. The wound is sutured and a dressing applied; nothing further is necessary.

Post-operative Care and Course

We have never had any trouble with suppuration or infection of any sort in any of our cases, and at the end of the operation no sign of any change in the bone can be seen. We have taken audiograms daily as a matter of interest. Immediately after the operation the hearing

is depressed, but in the course of a week or ten days it gradually returns. The post-operative deafness is of perceptive type, and due to disturbance of the cochlea. There is vertigo, and the paralytic nystagmus persists for some days. Pain is usually very slight, but two patients complained of moderate pain which came on a few days after the operation and lasted some days. No signs of any unusual damage could be detected to account for this. Tinnitus is sometimes relieved, but is occasionally increased at first. The common feeling of fullness or bursting in sensation in the ear, of which so many patients complain, usually disappears very quickly. Very wide fluctuations in post-operative hearing have been observed.

Results

We have now treated 40 cases. The results are summarized in the accompanying Table.

These results can be achieved only by applying sufficient ultrasound to the sensory neuroepithelium of the vestibular organ to render it functionless, and at the same time to improve the labyrinthine circulation to such an extent that some of the damaged cochlear structures can recover their function. If too much power is used the cochlear tissue may be further damaged, resulting in increased deafness and tinnitus. If too little power is used some vestibular function may remain and cause persistent or intermittent vertigo. From our results it appears that the more severe the depression of vestibular function, as shown by caloric and other labyrinth tests, before operation, and the worse the deafness, the smaller is the dose of ultrasound that is required to destroy the vestibular end-organ, and the more likely it is that the cochlea will also suffer some permanent damage.

It seems that incomplete destruction of the vestibular apparatus may suffice to relieve the patient of major Ménière attacks, but in some cases a second application has been necessary to abolish the vertigo completely. In order to establish a dosage standard for the amount of ultrasonic power needed in different cases, the total energy applied is recorded in joules. It is probable that the damage to tissues from intermittent application of ultrasound, as used in this technique, is not an exact summation effect. Some recovery takes place in the short intervals used for tuning, and more total energy is required than if the application had been continuous. This is observed particularly in the early stages, when paralysis has been present for several minutes, but irritative nystagmus returns after the few seconds' rest when the treatment is reapplied. On one occasion this recurred so many times that a continuous application of eight minutes was used at 8 watts/sq.cm. before persistent paralysis of the vestibular end-organ was obtained.

If the patient complains of pain during the treatment the head must be withdrawn at once and the output and temperature rechecked. Even when the surface cooling is efficient there is probably some temperature rise in the deep part of the bone, but the discomfort is mainly due to the mechanical effect of the ultrasonic vibrations on the temporal bone. There is great variation in the tolerance of different patients. Some object to the use of the hammer and gouge and some to the noise of the drill, while some are intolerant of the irritative vertigo of the early stage and others of the ultrasonic pain of the higher powers. During the operation it is sometimes

necessary to supplement the basal sedation by intravenous injection of sedatives, and for this purpose we use promethazine hydrochloride 12.5 mg.

Until it is possible to assess the dosage needed for each patient by physical standards it will be necessary to continue to observe the final development of vestibular paralysis by the nystagmus. It is still necessary, therefore, to operate under local anaesthesia in order to be able to observe the eye reactions, and also the warning discomfort of the patient if the temperature should rise or the ultrasonic power be too high. When there is doubt about the end-point we have occasionally tested the labyrinth by cold caloric stimulus by syringing directly on the lateral canal with water at 20° C.

After the operation the full benefit of the treatment is not usually obtained until some weeks have elapsed, and it seems probable that three or even six months are necessary for the full recovery after the tissue damage resulting from the ultrasonics. It is not at all uncommon for patients to have minor Ménière attacks at intervals after the operation, and we have found that recovery of hearing will continue up to three months afterwards. During this time the patients are advised to avoid overloading themselves with fluid, and a restriction to 1½–2 pints (850–1,140 ml.) in the 24 hours, depending on the time of year, is imposed, together with the avoidance of salt, tea, and coffee, which are suspected of increasing endolymph secretion. We think that the beneficial effect on the cochlea and the relief of the feeling of fullness are due to the increased permeability of the membranous labyrinth. These patients are also put on to a supplement of vitamin B complex for three months after the operation. In this group of cases we have had one patient who developed facial paralysis during the operation, owing to a sudden rise in the temperature of the temporal bone.

Illustrative Case

A man aged 48, referred by Mr. R. G. Macbeth, was a very sensitive and tense individual, occupying an important executive post. He was incapacitated by severe and frequent attacks of fully developed Ménière's syndrome. He had a perceptive deafness of 23 decibels in the affected ear, with marked depression of the caloric responses on that side, indicating a canal paresis. He was rather apprehensive at the time of operation on July 25, 1960, but with some added sedation he settled down, and the lateral semicircular canal was exposed. Unfortunately he had a completely acellular mastoid, with a forward sinus and low dura, and the space between the fallopian canal, the dura of the temporal fossa, and the lateral sinus was so small that it would only just take the treatment rod, and there was very little space for a bath of saline round it. Treatment proceeded satisfactorily and irritative nystagmus appeared in a few seconds, but owing to the patient's sensitivity we were not able to increase the intensity above 4 watts/sq.cm. In spite of this, after eight and a half minutes paralytic nystagmus was fully established, and we were continuing with the treatment, when the patient suddenly exclaimed that his ear felt hot. A glance at the drip feed of the cooling irrigation saline showed that the flow had stopped. Before this could be re-established facial paralysis was observed. The treatment was stopped immediately, although only 630 joules had been used.

A search for the cause of the sudden arrest of the cooling fluid disclosed that the rubber tube connecting the saline vessel to the irrigating apparatus had been sterilized with the tubing kinked at one point, and although the flow was adequate while the rubber tube was hanging vertically down

it had stopped abruptly when the fluid vessel had been pulled backwards, stretching the tube. In spite of the low dosage employed the patient has had no more major attacks of Ménière's syndrome, and is very much improved, though still complaining of some instability. The hearing has improved to 10 decibels over the critical speech frequencies, and the facial paralysis is recovering satisfactorily.

As a result of this experience, which confirmed our theory that facial paralysis is most likely to be due to too much heat in the temporal bone, we now employ continuing monitoring of the temperature in the cooling fluid at the tip of the rod by thermo-couple with flexible tubing connecting it to the gauge. A member of the theatre staff continually watches this temperature gauge and adjusts the flow of the warm or cold coolant to maintain the temperature at a degree or two around 37° C.

Table of Results

Number of cases	40
Ménière attacks:	
Ceased	20
Diminished; not quite abolished	8
Attacks continued	3
Too recent for assessment	7
Hearing:	
Improved by 10 decibels or more	10*
Unchanged	18
Decreased	10
Too recent for assessment	2
Tinnitus:	
Ceased	10
Decreased	5
Unchanged	7
Worse	1
Caloric tests: still active with good result	4
Second application: two cases, both successful	
Dosage in joules:	
Maximum used	1,700
Minimum used	580
Duration of application of ultrasonics in the last 21 cases when full power was available	
Maximum	32 minutes
Average	21 minutes

* One patient improved from -45 to -12 decibels

Discussion

Although the number of our cases is small, and although we have had two or three disappointing cases where hearing has been worse rather than improved, there have been only two patients in whom hearing has been completely lost; in both of these there was a technical error in the preparation of the lateral canal. Apart from the one case of facial paralysis described above, we have not observed any facial damage at any time, and this major disadvantage of the original method of treatment seems now to have been eliminated.

On the other hand, at the present time this operation cannot be undertaken with safety without a great deal of instrumental control over the apparatus. In the first place the generator and treatment head need constant supervision by a trained physicist to ensure that the output is properly measured and controlled, and that failures in the apparatus do not occur during the course of the operation. Secondly, the theatre staff must watch the temperature of the bone surface and adjust the cooling fluid according to the temperature recorded by the thermo-couple. Thirdly, the attendant physicist must be able to tune the apparatus on the monitor at intervals of five minutes throughout the course of the application. Fourthly, a very skilled assistant is also needed who can watch the ocular reactions and facial muscle movements throughout the operation. At the present time we are engaged in experimental work to develop an apparatus which will

be very much simpler than the present one and which we hope will not require the services of so many physicists and trained assistants. It is our hope, too, that in due course it will be possible to assess the dosage required for each case, and thus relieve the surgeon of much of his anxiety, which cannot be avoided at the present time.

Summary

Ultrasonic radiation is employed to destroy selectively the vestibule and spare the cochlear end-organ in cases of Ménière's disease.

A modified Arslan-Federici generator and transducer is used. The lateral semicircular canal must be exposed under local anaesthesia to apply the ultrasonic radiation direct to the labyrinth. Liquid coupling and cooling are employed by continuous saline irrigation and the temperature is strictly controlled. Facial paralysis is the most serious complication and is usually due to excessive heating of the temporal bone, but it may also be due to the ultrasonics reaching the nerve. The apparatus employed requires calibration and monitoring by special apparatus if adequate power and a narrow and safe beam of ultrasonics is to be obtained. The dosage used has been measured in joules, but it is still necessary to decide by observation of the nystagmus when the destruction has been accomplished.

After the operation there is a temporary reduction in hearing acuity, but recovery to the pre-operative level, and in some cases to above this level, begins in a few days.

The results of the treatment of 40 cases by this method are given.

We are grateful to colleagues who have referred cases to us for treatment. Our thanks are due to Mr. Eatough for photography. We also wish to pay tribute to the hard work and enthusiasm of the nursing and resident medical staff of the E.N.T. department of the Bristol General Hospital who have made important contributions to this work. We acknowledge a research grant for apparatus from the Board of Governors, United Bristol Hospitals, and a research grant from the Medical Research Council.

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Some of Australia's biggest hospital and medical benefits firms have been linked in a national organization aimed at improving voluntary health insurance for the benefit of contributors. Five non-profit-making firms, covering five million people, have formed a new organization to be known as the Voluntary Health Insurance Council. The council will distribute information on the system of voluntary health insurance and will promote research with the idea of improving the system. The firms making up the council are the Hospital Benefits Association of Victoria, the Mutual Hospital Association of South Australia, and the Medical Benefits Fund of Australia, Ltd., in New South Wales, Queensland, and Tasmania. A spokesman for the organization has said that Australia's system of health insurance was almost unique and had attracted world-wide interest. More than £A.24m. was paid to members last year in hospital and medical claims. (Radio Australia News, October 3.)