The use of telemetering capsules in disorders of the alimentary tract

Part I A technique for recording pressure changes

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The search for a means of studying the activity of the gastro-intestinal tract with the minimum of upset to the patient has led to the development of miniature capsules requiring no direct connexion with external apparatus and which can be swallowed easily. One form of capsule contains a pressure transducer which modulates the frequency of a transistor oscillator powered by a small mercury cell within the capsule. Recording may be carried out continuously from the human alimentary tract as described by several groups both abroad and in Great Britain (Mackay and Jacobson, 1957; Farrar, Zworykin, and Baum, 1957; von Ardenne, 1960; Rowlands and Wolff, 1960; Connell and Rowlands, 1960a and b).

The widespread application of such techniques to clinical research is as yet limited by a number of problems which are under examination in Great Britain, in particular in London, in Sheffield, and in Edinburgh. Experimental studies using the radio telemetering capsules carried out at these centres have shown that the two most urgent problems requiring solution before routine procedures can be adopted are the localization of the capsule during transit in the alimentary tract, together with some means of assessing its rate of progress, and the problem of preserving the radio link with the capsule as it is tumbled about within the gastro-intestinal tract during digestive activity.

Methods of localization of the capsule fall broadly into two categories, namely, those relating the position of the capsule to the external features of the body by methods based on radio-location principles, and those relating the position of the capsule to certain parts of the alimentary tract itself, using radiographic contrast techniques. The results of determinations using the first method are not completely satisfactory because of the overlapping of various parts of the digestive organs. Concentrating on the second method, we have employed radio-opaque marker meals of bismuth carbonate, one

taken before the capsule and another after it, to differentiate certain parts of the alimentary tract (Smith and Ridgway, 1961). It is possible to obtain fairly precise information in this way, but should interpretation prove difficult the radiological technique may be improved by stereoscopy or by special positioning so that the risk of overlap is lessened. The total exposure to radiation from intermittent localization is small but for continuous tracking of the progress of the capsule radiographic methods cannot be used. The radiographic examination has therefore to be a restricted one; even so it is possible from one, two, or three films to relate retrospectively the capsule's progress to the record obtained during its transit from one site to another. In this way the localization problem has been partially overcome, and this paper recounts how we have approached the practical difficulties associated with the radio link.

THE DIRECTIONAL AERIAL PROBLEM

If a simple aerial loop is used to detect the radio signal, the strength of the radio link varies as the capsule changes its orientation with respect to the loop, because the weak electromagnetic field produced by the capsule transmitter has the usual dipole character, and is thus not uniformly distributed about the capsule (Fig. 1). The signal strength is greatest when the number of lines of force passing through the aerial loop is at a maximum; therefore if the capsule turns so that the field is aligned parallel to the plane of the aerial, the signal strength falls, sometimes to such a low value that insufficient electromagnetic energy is induced into the receiver to operate it correctly. This effect becomes more troublesome as the distance between the capsule and the aerial loop is increased. If in fact the signal falls below a critical level, the pressure indicator tends to fall to its resting or zero position.

FIG. 1. The nature of the electro-magnetic field produced by the capsule transmitter. The figures from 0 to 0.7 indicate the relative approximate signal strengths for various orientations which the aerial loop can assume at the same distance from the capsule in the dipole field.

FIG. 2. The upper tracing shows typical phasic pressure activity when the capsule was lying in the terminal small bowel. Some time later, when the capsule had moved into the right colon and another form of pressure wave should have been recorded, a series of short discontinuities was detected by a simple form of signal level monitor in the original apparatus, causing the pattern seen on the lower tracing. The confusing appearance of these artefacts made the development of a monitor for recording signal level necessary.

This excursion which appears on the pressure tracing does not then truly record the hydrostatic pressure surrounding the capsule and is an artefact caused by the breakdown in the radio link. Unfortunately, it was found that the nature of the positional or orientational changes experienced by the capsule was such that on our original apparatus (Smith and Ridgway, 1961) many of these artefacts could not be distinguished from some normal phasic pressure waves (Fig. 2).

METHOD

THE APPARATUS It is not easy to construct a receiver that is completely insensitive to the movements made by the capsule during transit of the bowel, although two groups claim to have built equipment with omnidirectional sensitivity (Jacobson and Lindberg, 1960; McCall, 1961). Whilst this is generally acknowledged to be the most desirable solution a relatively simple modification enables less elaborate equipment to be utilized if the aerial loop can be kept close to the subject's abdomen. Most hospital patients are content to sit quietly or lie in bed, perhaps reading or listening to the radio for the periods when recordings are being made. These periods may occupy the greater part of two or three days. A series of four simple aerial loops, mounted on a light flexible belt of foamed plastic material, is pinned unobtrusively under the top fold of the bedcover roughly positioned across the subject's abdomen (Fig. 3). Each is connected to the radio receiver through a simple manual selector switch which enables any one of the loops to be used for detection of the radio signal. It also allows a reference signal from a stable generator to be passed into the receiver for recalibration of the indicated basal level if this should change unexpectedly. A number of tests carried out on the receiver during continuous use showed that the long-term frequency stability was such that the indicated basal level is accurate to within 1 kc/s over periods of 48 hours or more.

The modified receiving equipment operates in a similar manner to a conventional receiver for frequency modulated broadcasts, but instead of having an audible output it produces, from the information sensed by the capsule as it passes along the alimentary tract, a continuous tracing of the variation of intraluminal pressure on a direct writing recorder. A synchronous record is made on an adjacent recording channel of the variation in level or amplitude of the radio signal incident on the antenna. A valve-operated switching device was incorporated into the recorder so that the pressure indicator should not fall to its resting position during the short breaks in the radio link when the signal strength falls below the critical level necessary for the correct operation of the demodulating circuits of the receiver. This effectively removed the artefacts due to movement shown in Fig. 2 (cf. Fig. 4). The operation of this 'memory device', although convenient in holding the pressure indicator steady during the periods of insufficient transmission of signals, briefly disconnects the aerial system and receiver so that there is a temporary loss of information. The duration of this

FIG. 3. The radio signal from the pressure-sensitive capsule can be detected using any one of the five loops seen on the bedcover. The loop selected for use at any one time is connected to the receiver which is accommodated on a bedside trolley through a manual selector switch seen on the lower shelf. The double channel direct writing recorder is seen on the left, above a reference frequency generator.

FIG. 4. (a) A double channel recording of the pressure variation (upper trace) and the signal level (lower trace) showing how the artefact (A) arises when the signal falls below the lowest continuous black line, which is the critical signal level.

(b) An electronic memory circuit removes the artefact from the pressure tracing thus 'smoothing' the recording during a period when the capsule is turning about in the body. Reference to the signal-level tracing enables the discontinuities in the information to be noted exactly.

FIG. 5. A polar diagram constructed in vitro, showing contour lines representing lines of equal signal strength. It shows the approximate positions of the two positions referred to in the text; suitable at (1) for recording pressure changes on the 'plateau' and at (2) for the observation of orientational changes at the 'edge' of the field.

period can be deduced by reference to the signal level (Δs) channel. These changes can, however, be applied to the detection of capsular movement, particularly orientational changes, and can be made to disclose, by the technique described below, the rhythm of these changes when they occur.

DOUBLE-CHANNEL RECORDING TECHNIQUE FOR PRESSURE AND MOVEMENT STUDIES The changes in signal level seen during continuous monitoring of pressure changes depend not only on the nature of the radio link but also on the characteristics of the receiver and the distance between the capsule and the aerial loop. By systematically varying the relative orientation of aerial loop towards a capsule (which was immersed in a bath of water to simulate the absorption effect of an equivalent amount of body tissue) positions of equal signal strengths were found and plotted (Fig. 5). From these results a polar diagram was constructed which enables us to evaluate roughly the way in which the signal level may be expected to change with various movements. The limitations of recording as a single variable what is effectively a complex of movements in three dimensions are obvious and must constantly be borne in mind during interpretation of the variations. At the moment, no information can be deduced in absolute terms of the quantitative movements of the capsule and a steady signal level cannot be considered to indicate that the position or the attitude of the capsule in space has not changed. An empirical study of typical changes seen during recordings made from patients using aerial loops at different positions and orientations has shown that at various sites the rhythmicity of the changes, when they occur, can be informative.

When the aerial is situated near to the axis of the

transmitter (Fig. 5, position 1) even quite large changes in the orientation of the capsule cause only small variations in the signal level, whereas if the aerial loop is sited so that its axis is almost at right angles to the axis of the transmitter a similar change in orientation would cause a signal level change almost equivalent to a full-scale excursion (Fig. 5, position 2). The second recording site, although providing a sensitive recording of orientational movements, leads to frequent discontinuities in the pressure recording since a large change causes the signal to fall below the critical minimum.

Drawing an analogy with topographical contours, we have termed the first position where the signal level changes are more gradual (the contour lines representing

FIG. 6. Records of pressure and orientational changes obtained from positions (1) and (2) in the same patient. The upper two tracings, Δp and Δs , were obtained on the plateau position (1); the record Δp shows pressure fluctuations, with signal level (Δs) remaining constant. The lower two tracings, Δp and Δs , were obtained at the edge of the field at position (2); the record Δs shows marked changes due to effects of movement. The upper record remains free from artefact because the signal level remains substantially above the critical level.

different signal strengths are further apart) the field 'plateau'; the second position where the signal level changes are more precipitous (the contour lines crowd together) we have termed the 'edge' of the field. By using the sharp gradients at the edge of the field, where the transmitting and receiving coils are almost at right angles, even the small movements of the capsule due to normal respiration can be detected. In the event of each of the four fixed loops failing to provide an appropriate signal level, a fifth aerial loop mounted on a mobile carrier can be used to search for a more suitable recording site. Figure 6 illustrates how recordings may be obtained

from positions 1 and 2. A recording of pressure (Δp) was obtained with the capsule within the small bowel; the record of signal strength (Δs) did not vary at this time. The recording position was later adjusted to a site at the edge of the field (comparable to position 2, Fig. 5). Movement or orientational effects are now disclosed by the abrupt rise and fall of the signal level, on the signal strength channel.

ESTIMATION OF ONWARD PROGRESSION In using this method of recording, certain features have been noticed which have frequently been helpful in completing the overall picture of the motor activity of the alimentary tract.

Generally, the outlying loop to the right gives a maximum signal when the capsule is in the terminal ileum, caecum, or right colon, whereas the outlying loop to the left is used more frequently when the capsule is in the distal transverse colon or small bowel. It is thus possible to gain some idea of the general onward progression of the capsule. The position of the capsule deduced in this way can only be approximate, and must be reasonable in relation to the time lapse since the capsule was swallowed. It must also be in conformity with previous and subsequent positions disclosed by radiographic methods.

A further phenomenon may be used to locate the capsule fairly accurately. It occurs when the capsule moves into a conical volume about 5 cm. in height based on the plane face of the aerial loop. Under these conditions the basal pressure level appears to undergo a step-like change to a higher level (Fig. 7). This could lead to serious incorrect conclusions as to the pressure within the bowel lumen, but when it occurs on the tracing the phenomenon is very obvious and can easily be both detected and corrected by switching to the next aerial loop. It occurs most frequently when the capsule is close to the abdominal wall and has been observed most

FIG. 7. The appearance of the 'overcoupling' artefact produced by switching at (a) and (c) to a loop which is close to the capsule causing a marked change in baseline. The artefact may be corrected and the true basal level restored by switching to another aerial loop, as at (b) or (d).

commonly when it is approaching the ileo-caecal valve. The phenomenon can usefully be employed to estimate, to an accuracy of 1 to 2 cm., the location of the capsule when it is near the body surface. Since it is essentially an effect depending on close proximity of capsule and antenna loop, we have termed it 'overcoupling'.

DISCUSSION

The external equipment for recording pressure changes relayed from the human alimentary tract by a radio-telemetry capsule is relatively simple. The capsules used by us were commercially produced, and since they are expendable, the cost is an important consideration. More general use of this type of investigation, and, therefore, increased production of commercial capsules, would lower the cost of these units, but until then it will remain an open question whether it is better to construct a telemetering capsule that will last indefinitely or to use expendable units in the hope that increasing demand will reduce the commercial price.

In order to foster the use of this useful and interesting technique of investigation we have sought to contribute to the solution of the two outstanding difficulties in its general application: first, by developing a method of radiological markers for the estimation of the capsular position within the intestinal tract (Smith and Ridgway, 1961); and secondly, by establishing a technique for the combined recording of pressure and movement or orientational changes. The modification in technique presented in this paper exploits the problem by sometimes allowing the orientational or movement changes to be recorded, as well as the associated pressure change, so enhancing the clinical significance of the results. Registration of movement in this way may disclose information important in the assessment of the functional activity of the gastrointestinal tract. It could also be used as a further parameter in the study of the pharmacological effects of drugs.

von Ardenne (1960) has used a method which is similar to ours, but which requires an aerial loop around the body. When recording positional movement of the capsule, this method does not permit selection of the most appropriate part of the field, which is dependent on the orientation of the capsule towards the aerial at any one time; this is best sought for by a movable antenna.

On the occasions on which it has been possible to record sequences of movement and pressure, some interesting observations have been made at the pylorus, in the small intestine, at the ileocaecal valve, and in the colon.

SUMMARY

A method for telemetering pressure changes within

the human alimentary tract by the use of a capsule containing a pressure-sensitive transducer and radio transmitter is described.

The method exploits a difficulty inherent in this new technique, namely, that of the maintenance of the link between radio transmitter and receiver.

A technique for the combined recording of pressure change and movement of the capsule is described.

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Part II The application to the study of human gastro-intestinal motility

The clinical application of the combined method of recording intestinal pressure change and movement from a telemetering capsule is the substance of this section.

METHOD

Before the capsule¹ is swallowed it is calibrated against a simple water manometer by sealing it in a glass vessel containing water maintained at body temperature. The frequency shift of the emitted radio signal is noted as small pressure increments are applied by a hand bellows. The relationship between pressure change and frequency shift has usually been found to be linear up to values of 70 cm. of water above atmospheric pressure.

Before calibration the capsule is warmed to just above body temperature for about 30 minutes, and the transmitter is activated by withdrawing, through a hole in the body of the capsule, a plastic pin which holds apart the battery contacts. This hole also serves to equalize the pressure of the air trapped inside the capsule to the atmospheric value on the day of the clinical test. It is then sealed with moisture-resistant tape and a little silicone grease is applied to the plastic diaphragm to help to prevent absorption of moisture from body fluids, which can lead to a slight distortion after a long period of immersion.

Patients are invited to participate in the test; they should so far as can be ascertained have no narrowing of the alimentary tract. The capsule is swallowed one hour after a marker meal of bismuth or dilute barium. Five hours after the first marker meal, a second meal is consumed; the pill is located by relating it to the shadow

of the second marker in the stomach or to the first, which should now be outlining the ileocaecal region (Smith and Ridgway, 1961). Two further radiographs are usually taken at about eight hours and 24 hours after the beginning of the test.

Recordings may be made continuously or intermittently as the capsule passes along the alimentary tract. It is generally best to plan intermissions to allow the patient to relax in what may amount to a 40-hour investigation, but, if so desired, recording may be continued throughout meals and while the subject is receiving visitors.

The capsule is normally swallowed in the morning after a light breakfast; alternatively, it may be swallowed on the previous evening with a length of thread attached to it, of sufficient length to allow it to pass overnight through the pylorus. The test can then be started the next day with radiographic confirmation that the capsule is in the first or second part of the duodenum; delay caused by waiting for the pill to traverse the pylorus is thus avoided.

A secondary site of delay after what is usually a fairly brisk transit through the small bowel may be encountered at the caecum. The capsule then passes along the colon until delayed at the rectum before being expelled. The patient's stools are collected until the capsule is identified and recovered; this is made easier if the capsule is passed before the battery activating the transmitter is exhausted. The battery life is variable, depending on the nature of the capsule components, but is usually between 35 and 70 hours.

RESULTS

STOMACH The stomach shows little or no phasic pressure activity when the capsule is lying in the

¹The capsule was manufactured by Solartron Ltd.