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The Rygg-Kyvsgaard Disposable Bubble Oxygenator

A report on the use of 136 Rygg-Kyvsgaard oxygenators at Guys Hospital, London.

IN 1956 Dr. Inge Rygg, of the Rigshospitalet Copenhagen, first used the Rygg-Kyvsgaard type disposable bubble oxygenator for clinical perfusion. First described by Rygg[1] in 1956 and since considerably developed, this disposable oxygenator is now in world wide use. The present oxygenator (Fig. 1) is produced in a range of three sizes.

The Bag consists of:—

1) A Venous Collecting Chamber— Bubble Oxygenator

This first section is the oxygenating column. At the column base blood enters from the vena-caval line and cardiotomy suction return. O_2 and CO_2 are dispersed through the length of the column from a gas dispersing tube immediately above the venous blood inlets. This gas disperser delivers a gas mixture through approximately 250 crater-like holes, the size being in the order of 0.005 to 0.008 of an inch. This produces a bubble size of the order of 2 mm diameter.

2) Defoaming Chamber

This is situated at the top of the oxygenating column and consists of a tightly woven pack of Polypropylene fibre mesh coated with silicone antifoam (approximately 0.007 mg/cm^2). Excess gases are blown off from the two gas vents which are situated at the top of the defoaming chamber. After defoaming the blood flows, by gravity, through a series of three fine mesh filters (mesh size 180 micron), the last two being incorporated within the arterial reservoir.

The oxygenator is supplied in a sterile pack, sterilised by Gamma irradiation at the Danish Atomic Energy Commission Research Establishment.

The Rygg-Kyvsgaard Bag As Used By Guys Hospital

At Guys Hospital a series of 136 Rygg-Kyvsgaard oxygenators have been used (see Fig. 2). The technique used is kept as simple as possible. Blood-free primes are achieved using a 5% Dextrose diluent at 25ml. per kilogram of patient body weight: the Dextrose is heparinised with 30 mgm per litre. Additions to the prime are Sodium Bicarbonate: 25 meq, and Mannitol: 100 ml of 12.5% solution. (This is regarded as part of the prime.)

Flow rates, which are kept flexible, are according to the high flow principle and usually vary from 2.2 to 2.6 litres per square meter of patient surface area. Normothermic bypass is favoured and this is generally maintained at 35°C to 37°C using both a blood heat-exchanger and a warm water mattress.

The arterial pressure is monitored throughout the operative procedure by radial artery cannulation. Post operatively a Tycos gauge is connected to the radial artery cannula and this allows for rapid and accurate assessment of

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Table showing mean HCO_3, pH and PCO_2 with standard deviations before, during and after operation.

		Patient	Machine	Start of Perfusion	End of Perfusion	30-60 mins.	1-3 hours
HCO_3 m.Eq.	Mean	23	21.5	23	24	23.6	24
	Dev.	3	2.5	1.5	1	1.6	2.5
pH	Mean	7.41	7.29	7.39	7.39	7.42	7.43
	Dev.	0.38	0.35	0.23	0.18	0.19	0.19
PCO_2 mm/Hg.	Mean	41.5	37	41	41	35	37
	Dev.	10	6	6	6	5	4

the blood pressure during the intensive care period. Central venous pressure is monitored by cannulating the basilic vein.

The oxygenator is supplied with a humidified gas mixture of 97% O_2 and 3% CO_2. The amount of gas delivered varies from between 2 litres to 8 litres per minute. When additional volume has to be added to the oxygenator during bypass, fresh citrate blood is used. The average amount added per bypass is 920 ml.

In an effort to reduce haemolysis resulting from suction, a positive pressure is maintained within the cardiotomy suction return system (10 to 12 mm/Hg). A positive pressure of approximately 5 to 6 mm/Hg is also maintained within the oxygenator.

The Rygg-Kyvsgaard oxygenator has been used with flows from 440 ml to 5.8 litres per minute. Perfusion times have varied from 12 minutes to 6½ hours (at 4 litres per minute). Average perfusion time is 110 minutes.

Results

Scattergram I shows PCO_2, pH and HCO_3 measurements for 31 patients, undergoing aortic valve replacement, at various stages of the operative procedure. *Table I* shows the mean of the scatter together with the standard deviation. S.D. = sum of the differences / number of observations - 1

Patient

These figures were measured before bypass was instituted.

i) HCO_3

Most of the results fall into acceptable limits. Figures under 20 meq could be explained by a low preoperative cardiac output, and those above 24 meq could be attributable to over-enthusiastic administration of sodium bicarbonate. However, we have no evidence to prove this.

ii) pH

Again, most of these figures fall into the normal range with the exception of a few high figures which could be due to respiratory acidosis.

iii) PCO_2

As the patients were on the ventilator when these blood samples were taken, it is interesting to note that there is a tendency to over-ventilation, as is indicated by the depressed PCO_2 figures. On the whole though most of the figures are within the acceptable range.

Machine

i) HCO_3

As 25 meq of sodium bicarbonate is added to the prime, the concentrated scatter with a mean of 21.5 is to be expected.

ii) pH

The scatter is within the normal range with a mean of 7.29. This slight depression is due to the low pH of standard Dextrose 5% solution (about 5.5 to 6.0).

iii) PCO_2

This is well within the normal limits and no comment is necessary.

Start and End of Perfusion

During the perfusion period the PCO_2 and HCO_3 are adjusted to a set normal value (PCO_2 - 35 to 45 mm/Hg and HCO_3 - 24 meq). By the controlled use of CO_2 it is possible to maintain the PCO_2 at the normal value. Sodium bicarbonate 8.4% (1ml = 1meq) is used to keep the HCO_3 as near to 24 meq as possible. The dosage is calculated using the formula: Patient weight in kilograms x Deficiency x 7/2 (This gives the dosage in meq). Table I shows that at the end of the perfusion the HCO_3, pH and PCO_2 are at our normal requirements and the standard deviations are very acceptable.

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Table showing mean oxygen saturation and haemolysis with standard deviation figures for various flows and times.

Time		Under 1 hour			1-2 hours			Over 2 hours		
Flow lit/min		1-3	3-4	4+	1-3	3-4	4+	1-3	3-4	4+
Oxygen % sat	Mean	97.75	97.3	97.2	98.5	96.8	96.5	98	95.7	95.5
	Dev	1.08	1.33	1.42	0.91	1.57	1.39	0	2.82	2.59
mgm/% Haemolysis	Mean	21.3	55.9	57.9	93.3	79.1	99.6	105	91.6	106.1
	Dev	11.9	31.1	25.8	51.7	45.7	49.8	91	48.1	47.6

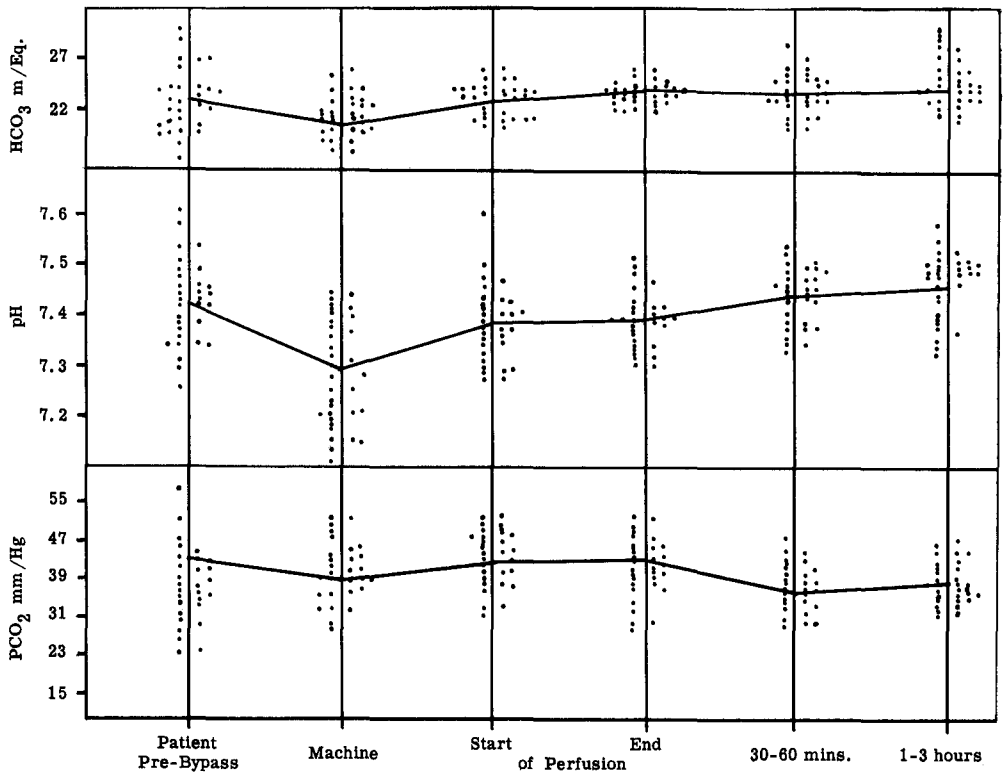

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Table showing HCO_3, pH and PCO_2 before, during and after operation

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Table showing oxygen saturation and haemolysis for various flows and times

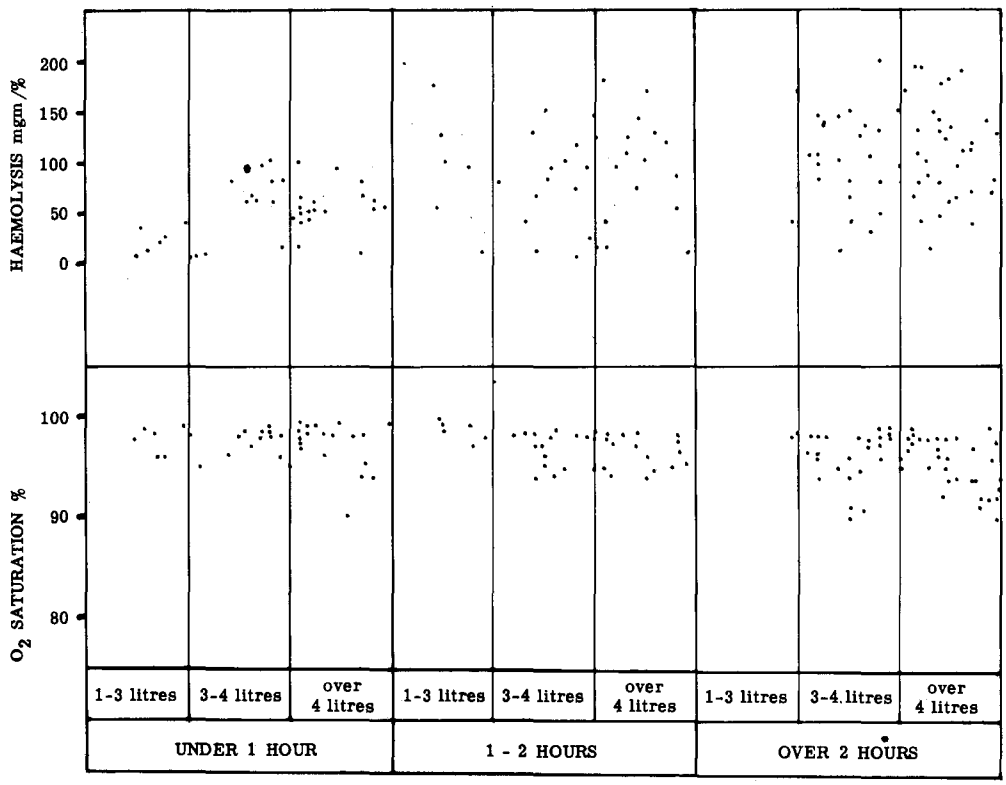

Figure 2.

Procedure	No. of Cases	Bypass Time
Aortic Valve Replacement	67	108 mins. Ave.
Aortic and Mitral Valve Replacement	14	100 mins. Ave.
Mitral Valve Replacement	15	107 min. Ave.
A.S.D.	13	29 mins. Ave.
Fallots	8	124 mins. Ave.
V.S.D.	6	70 mins. Ave.
Mitral and Tricuspid Replacement	3	145 mins. Ave.
Aortic Aneurism	2	118 mins. & 128 mins.
Triple Valve Replacement	2	202 mins. & 172 mins.
Pulmonary Stenosis	1	21 mins.
A.S.D. - V.S.D.	1	65 mins.
Pulmonary Embolectomy	2	63 mins. & 66 mins.
Sub-valvar Aortic Stenosis	2	36 mins. & 50 mins.

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FIGURE 2.

Post Perfusion

(30 - 60 minutes and 1 - 3 hours)

The scatter here on all three parameters is well within the normal range and the standard deviation is acceptable. *Scattergram II* shows the oxygen saturation figure and haemolysis for 136 perfusions at various flows with varying lengths of time.

Oxygen Saturation

The oxygen saturation figure for each case is the mean of the total number of determinations done during the perfusion period. Normally these are taken once every 20 minutes and are assessed on a Kipp Haemoreflector, the accuracy of which is plus over minus 1%. As can be seen from table II, all mean saturations are between 95% and 100%. The standard deviations are very acceptable. The gas flows into the oxygenator vary from 2 to 8 litres per minute.

Haemolysis

Haemolysis is determined using the Lissapol technique[2]. Scattergram II shows the post perfusion haemolysis level. As is to be expected the level of haemolysis increases directly with the length of perfusion. The standard deviations are mostly in the order of 50% of the mean figure and this wide scatter is due to some unknown factor other than the oxygenator.

Summary

One hundred and thirty six perfusions have been carried out at Guys Hospital using the Rygg-Kyvsgaard Disposable Bubble Oxygenator, with flows varying from 440 ml to 5.8 litres per minute and perfusion times between 12 minutes and 6½ hours. pH, PCO_2 and HCO_3 results for 31 cases of aortic valve replacement at various stages in the operative procedure have been tabled, and the results are very satisfactory. Oxygen saturation and haemolysis for 136 perfusions have also been tabled.

We have found that the Rygg-Kyvsgaard oxygenator has been satisfactory for the greater number of perfusions carried out at Guys and, combined with its disposability and inexpensiveness, it has proved to be an extremely useful oxygenator. In our experience we have found that its efficiency as an oxygenator decreases with flows over approximately 4000 cc's per minute, but in most cases oxygenation has proved to be adequate over this figure. At the time of publishing this report a total of 250 Rygg-Kyvsgaard oxygenators will have been used.

REFERENCES

[1] Rygg, I. H. and Kyvsgaard, E. (1956). Acta Chir. Scand. Vol. 112, Fasc. 6. Given at 6th Meeting of Skandinavisk Thoraxkirurgisk Förening, Denmark, October 1956.

[2] Shaw, S. (1967). J. Clin. Path. **20**, 95.