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A COMPARISON OF PULSE OXIMETRY VALUES IN OXYGEN DEPENDENT PATIENT(S), WITH SATISFACTION RATINGS OF DUAL PRONG VS SINGLE PRONG ADULT LOW FLOW NASAL CANNULA(S)

BACKGROUND: The current state of oxygen delivery systems is based on a dual-prong cannula design that was introduced in 1949. Dual nasal cannulas are used to deliver supplemental low flow oxygen to people in need of respiratory support. A study was conducted to determine patient inputs on the dual prong designs which included the following clinical issues: i) irritation of interior nostrils, ii) sore and irritation of upper lips, iii) sores around ears, iv) constriction around neck, v) displacement of dual prongs from nostrils, vi) self-consciousness while wearing dual prong devices, vii) removal of device when eating, and viii) use of protective pads to reduce skin irritation. The study was conducted to determine if a patient population found the current dual prong technology acceptable and if a new technology were introduced into that population, what features would be of importance to convert to new technology usage.

METHODS: In **121** patients currently on oxygen therapy, we looked at certain patient demographics, age, sex, flow rates, time usage of cannula, oxygen source-from continuous and or pulse dose flow devices and years of therapy. The population was asked a series of questions about their dual prong cannulas. The patients were then asked in a blinded fashion, if they would be interested in certain design features that may have a benefit to them. Following this, a new device was provided to the patients and additional information was gathered.

RESULTS: The population had an age range of 46-99, with an average age of 71.5 years. The population was 44% female and 56% male.

1.0) The following table provides the summary on: “Years on Oxygen Therapy”:

Length of time (Years) on Oxygen Therapy	Percentage %
Less than 1 year	19
1-2 years	19
3 years or more	62

2.0) The following table provides the summary on: “Duration between Change-out of Cannulas”:

Length of time (weeks) to change-out cannula	Percentage %
Every week	8
Every two weeks	16
Every four weeks	76

3.0) The following table provides the summary on “Flow Rates,” within the population:

Flow Rates (LPM)	Percentage %
1-2 LPM	48
2-3 LPM	29
3-4 LPM	16
4-5 LPM	5
5-6 LPM	2

The study had eight questions concerning the dual prong cannula. The study asked the patients to indicate which of the following clinical conditions occurred when using the dual prong cannula. A scaled response of: 1) Rarely, 2) Frequently and 3) Constantly, was used to record the patient’s frequency of issue(s) occurrence.

The questions were asked in this order: Do you have...

1) Sore / irritated nostrils interior?
2) Sore / irritation upper lip?
3) Irritation / sore around ears from tubing contact?
4) Constriction around neck by tubing?
5) Do prongs ever become displaced from nostril?
6) Self-consciousness wearing cannula, especially in public?
7) Need to remove cannula to eat or drink?
8) Need to use protective pads to reduce skin irritation around the ears?

Of the study patients, 10% of the patients, “Rarely” had issues with the dual prong device. Within the population, 90%*, had either, “Frequent” and/or “Constant” issues* with the dual prong devices, of which 57 % had “Frequent,” issues and 33 % had “Constant,” issues with the dual prong device.

4.0) The following table summarizes the rank order of the multiple dual prong issues recorded:

Rank Order of Dual Prong Cannula Issues	Number of issues in the Population	Percentage (%) of patients with issue
1) Do prongs ever become displaced from nostril?	81	67
2) Need to remove cannula to eat or drink?	51	42
3) Self-consciousness wearing cannula, especially in public?	44	36
4) Constriction around neck by tubing?	42	35
5) Sore / irritated nostrils interior?	38	31
6) Irritation / sore around ears from tubing contact?	37	31
7) Need to use protective pads to reduce skin irritation around the ears?	30	25
8) Sore / irritation upper lip?	11	9

*Within the 90% population that had issues, 79% had multiple issues (more than one) with the dual prong cannula.

The study then asked in a blinded fashion three questions concerning what clinical features and benefits would be of interest to them. The scaled response was based on a, “Yes or No” patient response.

The questions were asked in the following order:

1) Would you be interested in a newly designed nasal cannula which provided less pressure and friction to the face, ears and neck?
2) Would you be interested in a nasal cannula that is less visible?
3) Would you be interested in a nasal cannula that can be placed in either nostril?

The following table summarizes the blinded questionnaire responses:

Blinded questions on new features and benefits	Number of patients that responded, “No”	Number of patients that responded, “Yes”
Would you be interested in a newly designed nasal cannula which provided less pressure and friction to the face, ears and neck?	0%	100%
Would you be interested in a nasal cannula that is less visible?	0%	100%
Would you be interested in a nasal cannula that can be placed in either nostril?	0%	100%

The clinical monitor then provided a newly designed device and fit the device on the patients, connected it to an oxygen source, which the patient used in a clinical setting for five to fifteen minutes. Following the clinical use of the new design, the patients were asked the following questions, the scaled response was based on a "Yes or No," answers.

The questions were asked in this order:

1) Is the Easy 02, cannula more comfortable?
2) Does the Easy 02 feel stable and secure?
3) Would you be interested in using the Easy 02 when it becomes available?

Questions about a newly designed single cannula device to determine patient interest and possible conversion to a new design.	**Number of patients that responded, "No"**	**Number of patients that responded, "Yes"**
Is the Easy 02 more comfortable?	0%	98%**
Does the Easy 02 feel stable and secure?	1%	99%
Would you be interested in using the Easy 02 when it became available?	2%	98%

** 2% of the patients answered the: "same," to the question.

5.0) Pulse Oximetry Subset Analysis on Patient(s) using Continuous Oxygen Therapy

In cases where patients were on 24 hour, 7 days a week oxygen therapy, the clinical monitor gathered a base-line Pulse Oximetry (POX) reading for the dual prong device. Following a time constant of approximately 15-30 minutes, then following the use of the Easy 02 single cannula, a second POX reading was taken.

Gas supplied was 100% oxygen, utilizing both continuous tank source oxygen (45 patients) and pulse dose source oxygen devices (25 patients). The POX readings were taken using a calibrated SeQual Pulse Oximeter, model # 7588 (www.sequal.com). The flow rates were per the patients prescribed therapy and were recorded on the case report form.

The sub-population contained 70 patients with an average age of 70 and consisted of 20 female and 50 males. The patients were in a relaxed position and had stable respiratory rate for both POX reading.

The aim of the sub-analysis was to determine if there was any abrupt change of the delivered oxygen flow between the two devices using comparative POX readings.

The following table outlines the data gathered:

Description of Events	Number of Patients	% of Patients
Patients with equal POX reading to (baseline) dual prong reading	29	41.5
Patients with positive POX reading to baseline reading	40	57
Patients with negative POX reading to baseline reading	1	1.5

In a subset analysis of certain "Flow Rates" categories (LPM) the following POX ranges and average flow rates were calculated:

	Flow Rates		
POX Delta(s)	**1-2 LPM**	**3-4 LPM**	**5-6 LPM**
POX =	15	12	2
POX +	23	15	2
POX -	0	1	0
Avg POX increase	1.31%	1.46%	1.07%
Range POX	0% + 3.06%	-1.03 + 3.13%	0% + 1.10%

STATISTICAL ANALYSIS:

UPODS used a third party statistician to determine statistical methods and to perform the analysis.

The results were separated into two groups according to device system and POX reading. In each group means and standard deviations (SD) were calculated. Comparable groups were tested against each other using non-independent *t-tests*. Probability values less than 0.05 were considered to be significant.

The statistical hypothesis were defined as:

Null Hypothesis: Both delivery methods, on average deliver the same amount of oxygen. Hence we assume the Mean POX measure difference will be zero.

$$\text{mean}(\text{POX measure method 1-POX measure method2}) = 0$$

Alternative Hypothesis: The second method (Easy 02) is more efficient oxygen delivery method than the first method (Dual Prong). Hence the 2nd method will have a higher POX score; the Mean POX measures difference, as defined will be negative.

mean(POX measure method-POX measure method2) <0

Seventy (70) subjects received a single POX test using the two oxygen delivery methods. The two POX measurements values are not considered independent but paired by subject identity. Hence the analysis utilized the Paired *t-test* as the Hypothesis Test using the following formula:

$$t = \frac{\Sigma d}{\sqrt{\frac{n\left(\Sigma d^2\right) - \left(\Sigma d\right)^2}{n-1}}}$$

The following table provides the calculated POX Means and SD for the Easy 02 and Dual prong devices.

N=70	Mean	SD
Series 1 = Dual	95.49	2.13
Series 2 = Easy 02	96.21	1.99

RESULTS AND CONCLUSIONS:

Mean difference in POX measures =-0.73
95% confidence Interval -0.50 to -0.95
t-statistic = -7.65
Degree of freedom: df=69
1 tailed p-value p < 0.00001

Hence we reject the Null Hypothesis and accept the Alternate Hypothesis. Of the two data sets (Dual vs Easy 02), the analysis shows a high statistical significance that the Easy 02 delivers more oxygen in the 70 patients.

INTERPRETATION: The study has demonstrated that the dual prong design has many features that are highly dissatisfying (Frequent and or Constant issues) within the patient population. The patient population is one hundred percent in agreeance that they are open to new clinical features and benefits for their oxygen delivery systems. When introduced to a new human factors approach to oxygen delivery systems the patients were very interested in converting to a more comfortable, stable / secure, less invasive, less visible—ergonomic single cannula design. We found that the single cannula devices provided higher statistically significant POX readings when compared to dual prong POX readings across flow rate categories within a defined patient population and across both continuous and pulse delivery type devices.

APPENDIX A: UPODS CASE REPORT FORM

UPODS CLINICAL CASE REPORT FORM

Initials of Patient: _____

Age: _____

Sex (Circle one) Male Female

How long have you been on Oxygen Therapy? (Circle one):

Less than 1 year 1-2years 3 years or more

How often do you change your nasal cannula with a new one? (Circle one)

Every week every two weeks once a month

What Oxygen flow rate do you use? (Circle one)

1-2 LPM 2-3 LPM 3-4LPM 4-5LPM 5-6LPM

Please indicate which of the following occur as a result of your use of the dual prong cannula:

	RARELY	FREQUENTLY	CONSTANTLY
Sore/irritated nostril interior			
Sore/irritated upper lip			
Irritation/sores around ears from tubing contact			
Constriction around neck by tubing			
Do prongs ever become displaced from nostril			
Self-conscious wearing cannula, especially in public			
Need to remove cannula to eat or drink			
Need to use protective pads to reduce skin irritation around the ears			

Nasal Cannula Features:

1. Would you be interested in a newly designed nasal cannula which provides less pressure and friction to your face, ears and neck?

(Circle one) Yes No

2. Would you be interested in a nasal cannula that is less visible? (Circle one)
Yes No

3. Would you be interested in a nasal cannula that can be placed either nostril?

(Circle one) Yes No

REVIEW THE UPODS EasyO$_2$ NASAL CANNULA AT THIS TIME, AND FIT EasyO$_2$ DEVICE ONTO THE PATIENT.

1. Is the EasyO$_2$ cannula more comfortable? Yes
   No
2. Does the EasyO$_2$ feel stable and secure? Yes
   No
3. Would you be interested in using the EasyO$_2$ when it becomes available? Yes
   No
4. How would you improves the EasyO$_2$ Cannula?
   _____
   _____
   _____

Clinical Monitor Measurements Information:

SPO$_2$ on dual prong device_____
SPO$_2$ on **EasyO$_2$** device _____
Oxygen Flow Rate _____

Signature of Clinical Monitor: _____ Date: _____