Original Research Paper

Volume - 11 | Issue - 02 | February - 2021 | PRINT ISSN No. 2249 - 555X | DOI : 10.36106/ijar

Anaesthesiology

UTILITY OF SUPRA-GLOTTIC AIRWAY DEVICE IN CRITICAL CARE UNIT CARE UNIT.

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ABSTRACT **Background:** Study was designed to evaluate the feasibility of I-Gel for short term mechanical ventilation in patients admitted in ICU and to compare with the endotracheal tube in terms of haemodynamic changes, and lung mechanics. **Methods:**Total 40 patients with the age of 16 -65 years of either sex who required short term of mechanical ventilation up to 3 hours, were randomized allocated into two groups i.e. Group A and Group B. In group A, the appropriate size of I-gel was used with standard technique. In group B, after direct laryngoscopy an appropriate size endotracheal tube was introduced in the trachea. Blood pressure, Heart rate, Airway pressure, Static compliance and (PaO2/FiO2) ratio and complications were recorded. **Results:** Mean insertion time for i-gel and ETT was [12.53±3.2sec] and [16.60±2.4sec] respectively. We did not found any statistically significant changes in heart rate and systolic BP while diastolic BP was noticed to be increased with time in group A. Mean P/F ratio in both groups compared to baseline, increase with time which was higher in Group B as compared to Group A. The mean Ppeak in both groups, increase with time and was slightly higher in Group B as compared to Group A. Static Compliance was lower in Group B than Group A at all periods. Mean duration of ventilation and ICU stay were comparable and not statistically significant. **Conclusion:** For the short term ventilation i-gel can be used as safe alternative to endotracheal intubation in selected patients. It requires less amount of sedation so early withdrawal can be possible and less chances of VAP and other complication of prolong ventilation.

KEYWORDS :SAD, Mechanical Ventilation, I-gel

INTRODUCTION

The I-gel is non-inflatable supraglottic airway device designed for spontaneous or intermittent positive pressure ventilation. It was introduced into clinical practice in the United Kingdom in 2007 and is made of a thermoplastic elastomer, a soft gel-like substance[1]. It has easier insertion and uses, minimal risk of tissue compression and no position change after insertion[2] It has a widened, flattened stem with a rigid bite block that acts as a buccal cavity stabilizer to reduce axial rotation and mal-positioning, and a port for gastric tube insertion[3]. It is a latex-free device, and less expensive than other Supraglottic devices (SGD). The gold standard for definitive airway remains endotracheal intubation, but because of minimizing interruptions to chest compression and to maximize coronary and cerebral perfusion pressure, supraglottic airway devices could be a good substitute. The difficult airway society guidelines recommend using laryngeal mask airway to secure ventilation and oxygenation after failed optimized attempts at direct laryngoscopy[4]. The use of SGD during anaesthesia for spontaneously breathing patients was also reported[5]. There are case reports on the use of SGD during pressure-controlled ventilation in ICU for short term ventilation[6].

This prospective randomized study planned to evaluate the feasibility of I-Gel, a supraglottic device for short term mechanical ventilation in ICU patients and to compare its efficacy with the endotracheal tube in terms of haemodynamic changes, and lung mechanics. The secondary objective was to compare complications, duration of mechanical ventilation and duration of stay in ICU.

Method

After approval of the institutional ethics committee, this prospective randomized controlled study was conducted in the Department of Anesthesiology at King George Medical University from September 2016 to August 2017. Total 40 patients with the age group of 16 -65 years of either sex who required short term of mechanical ventilation up to 3 hours such as post-operative patients, seizure disorder patients in the postictal phase admitted in the intensive care unit were included in the study. Any patients with signs of irreversible brain injury, end-stage renal, cardiac, and hepatic failure, severe hypoxemia, risk of gastroesophageal reflux, Body mass index more than 30 kg/m^2, neck pathology, predictors for difficult intubation, mouth opening less than 20 mm, APACHE score-II more than 20 were excluded from the study.

All 40 patients were equally divided (20 each) randomly in two groups (Group A: Supraglottic device i.e. I-gel, Group B: Endotracheal tube) using a computer-generated randomization. Allocation concealment was done using sequentially numbered opaque sealed envelopes. All patients in either groups were anaesthetized with inj. Fentanyl 1µgm/kg , inj. Midazolam 0.05 mg/ kg , inj. propofol 1.5 to 2.5 mg/kg titrated to their hemodynamic status. After checking adequate bag-mask ventilation, injection Vecuronium 0.1 mg/kg was given and patients were ventilated for 3 minutes.

In group A, the appropriate size of I-gel was inserted with standard technique. Then patients were connected to a ventilator with appropriate settings. A nasogastric tube was inserted in the gastric channel of I-gel. Any patients with significant tidal volume loss were excluded after two attempts for correction. In group B, direct laryngoscopy was done using a Macintosh blade size 3 or 4 and vocal cords were visualized. An appropriate size endotracheal

tube was introduced in the trachea. Then patients were connected to a ventilator with appropriate settings any patients who could not be intubated in two attempts were excluded from the study.

Sedation in ICU was maintained with continuous infusion of inj. Fentanyl 0.05-0.08 microgram/kg/min. and midazolam (1-2 microgram/kg/min.) or inj. Propofol (5-30 microgram/kg/min).

The systolic blood pressure (SBP), diastolic blood pressure (DBP), Heart rate (HR) at baseline Peak airway pressure (PAP), Static compliance (SC) and P/F ratio (PaO_2/FiO_2) were recorded before intubation or insertion of i-gel at 1 hour, 3 and after removal at 1 hour, 12 hour and 24 hours. All patients were observed for any complication related to airways such as Dislodgment, gastric insufflation/aspiration, sore throat and laryngospasm. Patients were ventilated till condition improved and no further mechanical ventilation required however the duration of ventilation was limited to a maximum of 8 hours to i-gel [7,8]. If any patients required prolonged ventilation more than 8 hours then

SAD was removed patient in group A was intubated with an endotracheal tube of appropriate size and were excluded from the analysis.

Sample size and Statistical Analysis

PS Power and Sample Size Calculation Software (version 3.0, January 2009, Noderivs 3.0 United States license) were used to calculate the sample size for the present study using the " hemodynamic (mean change in systolic blood pressure)" as the primary outcome variable.[14] Considering the difference of 25 mmHg in mean change in systolic blood pressure during extubation between I gel group and endotracheal with level of confidence of 95%, an alpha error of .05 and a power of 80%, we calculated sample size of 16 patients per group using formula for non-inferiority trial for continuous data. To compensate drop-out and non-response rate, we decided to recruit 20 patients per group.

SPSS 17.0 (SPSS Inc, Chicago, Illinois) for the window was used for statistical analysis. Shapiro Wilk"s test was used to test the normality of the data. Continuous data were summarized as Mean ± SE (standard error of the mean) while categorical in frequency and %. Continuous groups were compared by independent Student's t test. For categorical variables Chi-square test or Fisher exact test was used. All statistical tests were two tailed and P<0.05 was considered statistically significant

RESULTS:

Total 39 patients completed study and included in analysis. One Patient was excluded from Group A as the patient required prolonged ventilation.

Both groups were having comparable demographic characteristics (Age, sex, weight and APACHE 2 score) (**Table 1)**. In Group A, mean SBP did not change (p>0.05) with its baseline at any time point. While in Group B, patients showed significantly higher SBP compared to baseline. **(Figure 1)** In both groups, the mean DBP were higher significantly with respective baseline. However, it did not differ (p>0.05) between two groups at all periods. In both groups had the significantly (p<0.001) lower mean HR at all periods as compared to baseline value. However, between groups, it did not differ (p>0.05).

The P/F ratio of two groups over the periods is summarized in **Table 2**. In group A, it differ and higher significantly (p<0.001) at from 3 hr after intubation to till end while in Group B, it differ and higher significantly (p<0.001) at from 1 hr after intubation to till end as compared to respective baseline. However, at other periods, it did not (p>0.05) differ between the two groups i.e. found to be statistically the same. The peak airway pressure (PAP) of two groups over the periods is summarized in **figure 2**. In both groups, the mean PAP increase with time and the increase was evident slightly higher in Group B as compared to Group A. However, it did not (p>0.05) differ between the two groups at all periods i.e. found to be statistically the same. The mean Static Compliance SC remains comparatively lower in Group B than Group A at all periods (i.e. from 1 hr after intubation to at removal) **(Figure 3)**. In Group A, the mean SC differ and significantly (p<0.01 or p<0.001) higher at 3 hr after intubation and at removal as compareto at 1 hr after intubation. In contrast, in Group B, it did not (p>0.05) differ as compared to at 1 hr after intubation at all periods i.e. found to be statistically the same.

The Ventilation time and ICU stay of two groups is summarized in **Table 3** and on Comparing Student's t test showed similar (p>0.05) ventilation time and ICU stay between the two groups though it was 1.9% and 6.9% higher respectively in Group B as compared to Group A.

The complications during ventilation and after removal of airway of two groups are summarized in **Table 4**. In both groups, complications viz. gastric insufflation and dislodgement were found absent (100.0%) in all patients. In contrast, in Group B, the laryngospasm was found present in 1 (5.0%) patient but in Group A, it was absent (100.0%) in all patients and the difference was also insignificant (p>0.05). Conversely, sore throat was present in 2 (10.5%) patients in Group A while 1 (5.0%) patient in Group B but the difference did not reach statistical significance i.e. found to be statistically the same. In both groups endotracheal intubation was found absent in all the patients at all the periods, i.e. both group A and B were comparable (100.0%)

DISCUSSION

The introduction of Supraglottic Airway Devices in clinical practice revolutionized the airway management and has been recommended for use in maintaining airway patency as it has added advantage of improved haemodynamic stability, reduced anaesthetic requirement for airway tolerance, lower frequency of coughing and improved oxygen saturation during emergence. In our study, i-gel is a relatively new, single use, noninflatable, SAD has been compared with ETT to assess their performance in artificially ventilated adult patients particularly in an Intensive Care setting. Belgin Akan, Deniz Erdem, Mahinur Demet Albayrak, Esra Aksoy, Fatma Akdur, Nermin Gogus et al report a case in which they use SAD(I-gel) They did not encounter any problem in mechanical ventilation lasting for 48 h in PCV mode. There findings show that the I- gel can be used in order to obtain airway control and thereafter maintaining mechanical ventilation in difficult tracheal intubation cases in ICUs.

In our study demographic profile (age, sex, body weight) and APACHE SCORE II between two groups was comparable i.e. statistically insignificant (p>0.05). Similar result was obtained by other group of investigators in large number of patients[9]

The airway insertion and intubation were uncomplicated in all the patients and our data showed mean insertion time for i-gel and intubation with ETT was [12.53±3.2sec] and [16.60±2.4sec] respectively. The result was statistically significant and it was higher in group B (ETT) than Group A (i-gel). Our observation was similar to some previous studies such as Anjan Das et al.

We did not found any statistically significant changes in systolic blood pressure (SBP) while diastolic blood pressure (DBP) was noticed to be increased with time in group A i.e. i-gel throughout study interval. Similar statement was also concluded in few other studies also[6,9]. But in group B i.e. ETT, the changes were statistically significant in both systolic and diastolic blood pressures throughout the interval but as compared to group A increase in SBP was statistically significant and higher in group B.

The changes in heart rate from baseline when compared between two groups were statistically insignificant. However, the mean heart rate was decreased within both the groups throughout study interval. Thus statistically significant changes were observed in heart rate in group A and B as compared to baseline. Ismail et al[10] did a study to measure haemodynamic responses in 60 patients.They divided patients into three groups receiving lma classic, i-gel, ETT and found that i-gel provides better stability of haemodynamic system.

In this study mean P/F ratio in both groups compared to respective baseline, increase with time which was higher in Group B as compared to Group A. In Group A, it is different and significantly higher (p<0.001) at 1 hr after insertion. While in Group B, it was highly significant (p<0.001) at 3 hr after intubation. However, at other periods, it did not differ between the two groups i.e. found to be statistically the same (p>0.05). As evident from above mentioned observation, after mechanical ventilation both groups showed improvement in oxygenation. Jaranzadeh et al.[11]2016 studied role of ventilation mode using a laryngeal mask airway during gynecological laparoscopy on lung mechanics, hemodynamic response and blood gas analysis. They found that PaO_2 was significantly higher after 10 and 15 min in VCV (volume control ventilation) group compared to PCV (pressure control ventilation) group (p=0.005 and p=0.03, respectively).The end tidal CO_2 showed significant increase after 10 and 15 min in VCV compared to PCV group.

On comparison of the mean peak airway pressure (PAP) in both groups, increase with time and was slightly higher in Group B as compared to Group A. However, it did not (p>0.05) differ between the two groups at all periods i.e. found to be statistically insgnificant. Sidiqui et al.[12] found Average PAP were 16.21 ± 1.78 cm H_2O which were adequate for controlled ventilation.

D. Olzdamar et al.[13] 2010 compared classical LMA with ET tube, change in PAP, SPO_2, and ET CO_2 levels was Insignificant among groups.

In our study static Compliance (SC) was lower in Group B than Group A at all periods (i.e. from 1 hr after intubation to removal). In i-gel group SC was significantly (p<0.01) higher at 3 hr and at removal as compared to at 1 hr.Conversely, between groups, compliance was significantly lower (p<0.01) in Group B. Russo et al[14] compared i-gel®,

LMA Supreme®, and Laryngeal Tube Suction-D found i-gel® with 95% insertion success rate and the highest airway compliance. Sharma et al[15] compared respiratory mechanics of I gel and LMA proseal found that PLMA formed better seal but dynamic compliance was higher with the i-gel ($p<0.05$).

In our study, mean duration of ventilation and stay in ICU were almost comparable among groups with no significant statistical difference. It showed that in our study there was no effect of type of airway on overall status of the ICU patients.

In both groups, complications viz. gastric insufflation and dislodgement were found absent (100.0%) in all patients. In contrast, in Group B, the laryngospasm was found present in 1 (5.0%) patient but in Group A, it was absent (100.0%) in all patients and the difference was also insignificant ($p>0.05$). Conversely, sore throat was present in 2 (10.5%) patients in Group A while 1 (5.0%) patient in Group B but the difference did not reach statistical significance i.e. found to be statistically the same. Luce et al.[16] compared SAD vs tracheal intubation in children:a quantitative meta-analysis of respiratory complications: During recovery from anesthesia, the incidence of desaturation (OR= 0.34 [0.19–0.62]), laryngospasm (OR = 0.34 [0.2–0.6]), cough(OR = 0.18 [0.11–0.27]), and breath holding (0.19 [0.05–0.68]) was lower when laryngeal mask airway was used to secure the airway. Jadhav PA et al.[17] 2015 compared I-gel and LMA proseal in anaesthetized spontaneously breathing patients there were no significant differences in demographic and hemodynamic data. Sidiqui et al.[12] reported that after removal of I-gel no blood staining on device was noted and coughing was observed in 6% patients and sore throat was noted in only one case after 24 hours of surgery. Hence, i-gel can be a safe and suitable alternative to ETT.

So we can say that Patients in both the groups were ventilated properly and there was no influence of type of airway used on overall morbidity of patient in intensive care settings.

CONCLUSION

For the short term mechanical ventilation i-gel can be used as safe alternative to endotracheal intubation in selected patients. By avoiding intubation we can overcome the complication associated to endotracheal intubation and as it require less amount of sedation so early withdrawal can be possible and there are less chances of ventilator associated pneumonia and other complication of prolong mechanical ventilation.

Tables:

Table 1. Demographic Characteristics of Two Groups

Demographic Characteristics	Group A (N=19)	Group B (N=20)
Age (Yrs), Mean ± Se	30.95 ± 1.97	29.65 ± 1.70
Sex (Female: Male)	18 :1	19 :1
Weight (Kg) , Mean ± Se	53.37 ± 1.11	54.80 ± 0.78
Apache 2 (Score), Mean ± Se	18.00 ± 0.43	17.30 ± 0.44

Table 2. P/F ratio (Mean ± SE) of Two Groups over the Periods

Time period	Group A (n=19)	Group B (n=20)	p Value
Baseline	220.74 ± 2.90	221.25 ± 4.11	0.929
1 hr	231.42 ± 4.61	250.10 ± 5.08	0.004
3 hr	249.68 ± 4.8	260.90 ± 3.27	0.128
1 hr after removal	262.26 ± 2.55	272.75 ± 2.98	0.070
12 hr after removal	282.37 ± 4.92	291.75 ± 4.79	0.105
24 after removal	331.26 ± 3.57	346.30 ± 4.27	0.009

Table 3. Ventilation Time and ICU Stay (Mean ± SE) of Two Groups

Variable	Group A (n=19)	Group B (n=20)	t-value	p-value
Ventilation time (hrs):				
Mean ± SE	5.79 ± 0.22	5.90 ± 0.24	0.34	0.739
Range (min to max)	4 to 7	4 to 8		
Median	6	6		
ICU stay (days):				
Mean ± SE	3.21 ± 0.21	3.45 ± 0.22	0.78	0.441
Range (min to max)	2 to 5	2 to 5		
Median	3	4		

Table 4. Distribution of Complications during Ventilation and after Removal of Airway of Two Groups

Complications	Group A (n=19) (%)	Group B (n=20) (%)	p-value
Gastric insufflation:			
No	19 (100.0)	20 (100.0)	-
Dislogement:			
No	19 (100.0)	20 (100.0)	-
Laryngospasm:			
No	19 (100.0)	19 (95.0)	0.323
Yes	0 (0.0)	1 (5.0)	
Sore throat:			
No	17 (89.5)	19 (95.0)	0.517
Yes	2 (10.5)	1 (5.0)	

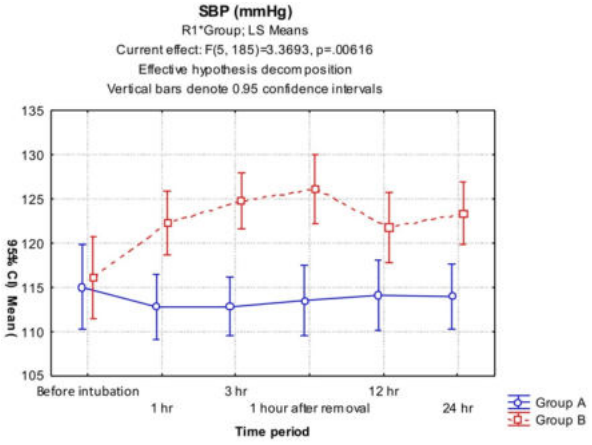

Figure 1. Mean SBP of Two Groups over the Periods

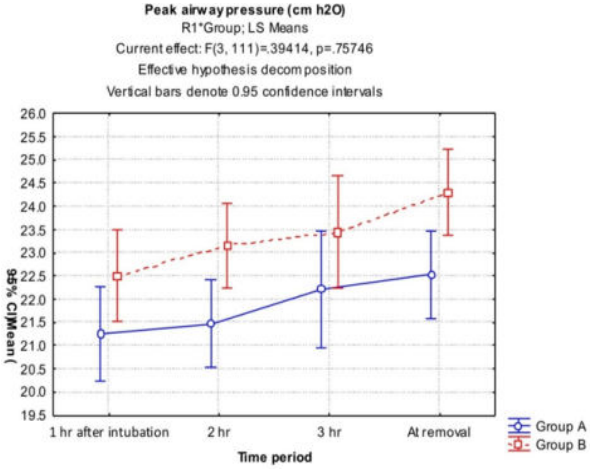

Figure 2. Mean PAP of Two Groups over the Periods

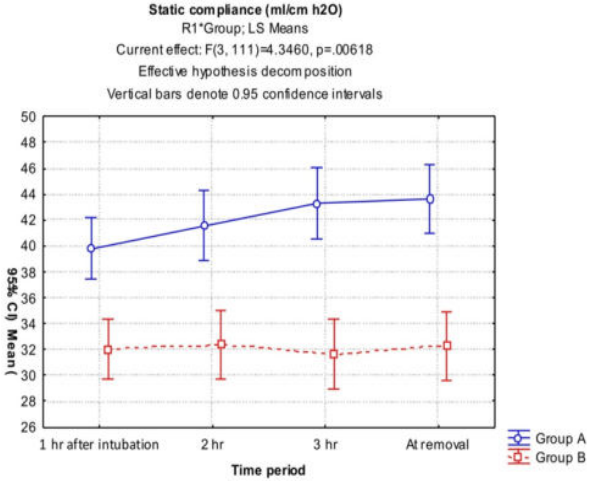

Figure 3. Mean SC of Two Groups Over the Periods

REFERENCES

1. Singh I, Gupta M, Tandon M. Comparison of clinical performance of i-gel with LMA-Proseal in elective surgeries. Indian J Anaesth. 2009;53:302–5.
2. Levitan RM, Kinkle WC. Initial anatomic investigations of the I-gel airway: a novel supraglottic airway without inflatable cuff. Anaesthesia. 2005;60:1022–6.
3. Gibbison B, Cook TM, Seller C. protection from aspiration and failure of protection from aspiration with the i-gel® airway. Br J Anaesth 2008; 100(3): 415-417
4. Weiss M, Engelhardt T. Proposal for the management of the unexpected difficult pediatric airway. Pediatric Anesthesia 2010; 20: 454–6.
5. Helmy AM, Atef HM, El-Taher EM, Henidak AM. Comparative study between I-gel, a new supraglottic airway device, and classical laryngeal mask airway in anesthetized spontaneously ventilated patients. Saudi journal of anaesthesia. 2010 Sep;4(3):131
6. Uppal V, Fletcher G, Kinsella J. Comparison of the i-gel® with the cuffed tracheal tube during pressure-controlled ventilation Br J Anaesth 2009;102(2): 264-8.
7. Emilio B. Lobato, Nikolaus Gravenstein, Robert R. Kirb Complications in Anesthesiology 3rd Edition
8. Brimacombe J, Shorney N. The laryngeal mask airway and prolonged balanced regional anaesthesia. Canadian journal of anaesthesia. 1993 Apr 1;40(4):360-4.
9. Das A, Majumdar S, Mukherjee A, et al. i-gel™ in Ambulatory Surgery: A Comparison with LMA-ProSeal™ in Paralyzed Anaesthetized Patients. J Clin Diagn Res. 2014;8(3):80–84. doi:10.7860/JCDR/2014/7890.4113.
10. Ismail SA, Bisher NA, Kandil HW, Mowafi HA, Atawia HA. Intraocular pressure and haemodynamic responses to insertion of the i-gel, laryngeal mask airway or endotracheal tube.European Journal of Anaesthesiology (EJA). 2011 Jun 1;28(6):443-8.
11. Jarahzadeh MH, Halvaei I, Rahimi-Bashar F, Behdad S, Nasrabady RA, Yasaei E. The role of ventilation mode using a laryngeal mask airway during gynecological laparoscopy on lung mechanics, hemodynamic response and blood gas analysis. International Journal of Reproductive BioMedicine. 2016 Dec;14(12):755.
12. Siddiqui AS, Ahmed J, Siddiqui SZ, Haider S, Raza SA. New single use supraglottic airway device with noninflatable cuff and gastric tube channel. Journal of the College of Physicians and Surgeons Pakistan. 2012 Jul 1;22(7):419-23.
13. Ozdamar D, Güvenç BH, Toker K, Solak M, Ekingen G. Comparison of the effect of LMA and ETT on ventilation and intragastric pressure in pediatric laparoscopic procedures. Minerva anestesiologica. 2010 Aug 1;76(8):592.
14. Russo S. G., Goetze B., Troche S, Barwing J, Quintel, Timmermann ALMA-ProSeal™ for Elective Postoperative Care on the Intensive Care Unit Prospective, Randomized Trial Anesthesiology 2009;111:116–21.
15. Sharma B, Sehgal R, Sahai C, Sood J. PLMA vs. I-gel: A comparative evaluation of respiratory mechanics in laparoscopic cholecystectomy. Journal of anaesthesiology, clinical pharmacology. 2010 Oct;26(4):451.
16. Luce V, Harkouk H, Brasher C, Michelet D, Hilly J, Maesani M, Diallo T, Mangalsuren N, Nivoche Y, Dahmani S. Supraglottic airway devices vs tracheal intubation in children: a quantitative meta.analysis of respiratory complications. Pediatric Anesthesia. 2014 Oct 1;24(10):1088-98.
17. Jadhav PA, Dalvi NP, Tendolkar BA. I-gel versus laryngeal mask airway-proseal: comparison of two supraglottic airway devices in short surgical procedures. Journal of anaesthesiology, clinical pharmacology. 2015 Apr;31(2):221.
18. Belgin Akan, Deniz Erdem, MahinurDemet Albayrak,Esra Aksoy,Fatma Akdur, Nermin Gogus Pressure support ventilation with the I-gel in intensive care unit:case report Rev. Bras. Anestesiol. vol.66 no.2 Campinas Mar./Apr. 2016.